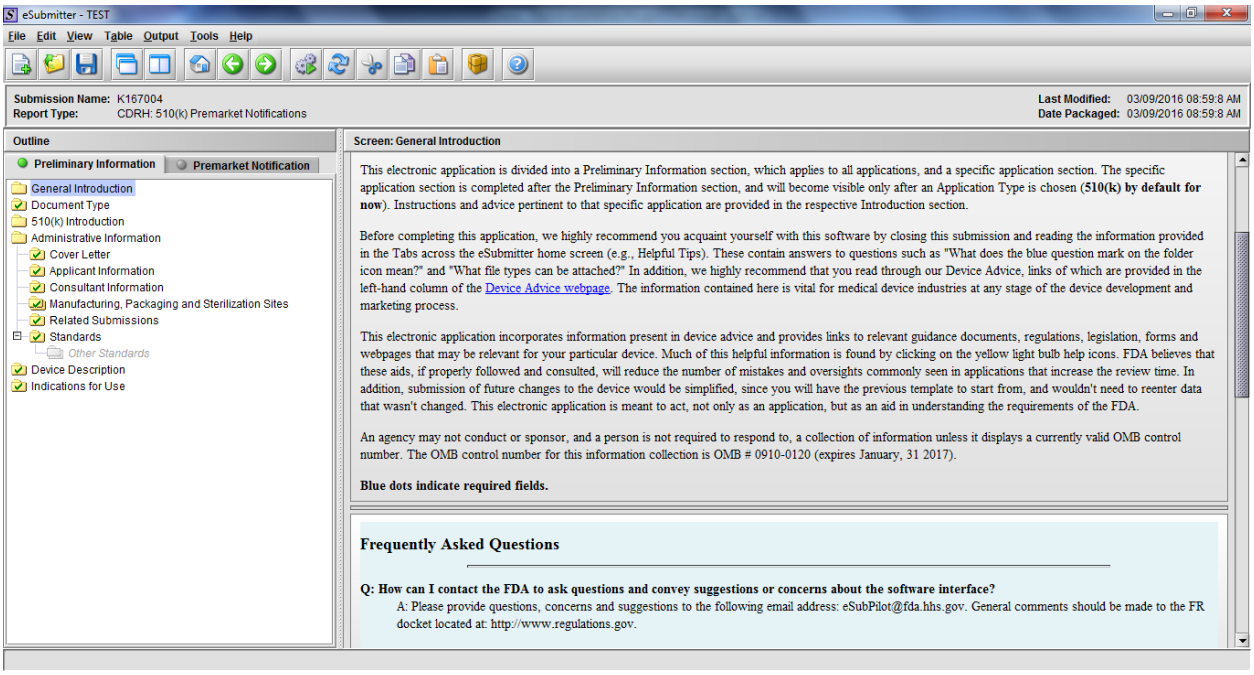
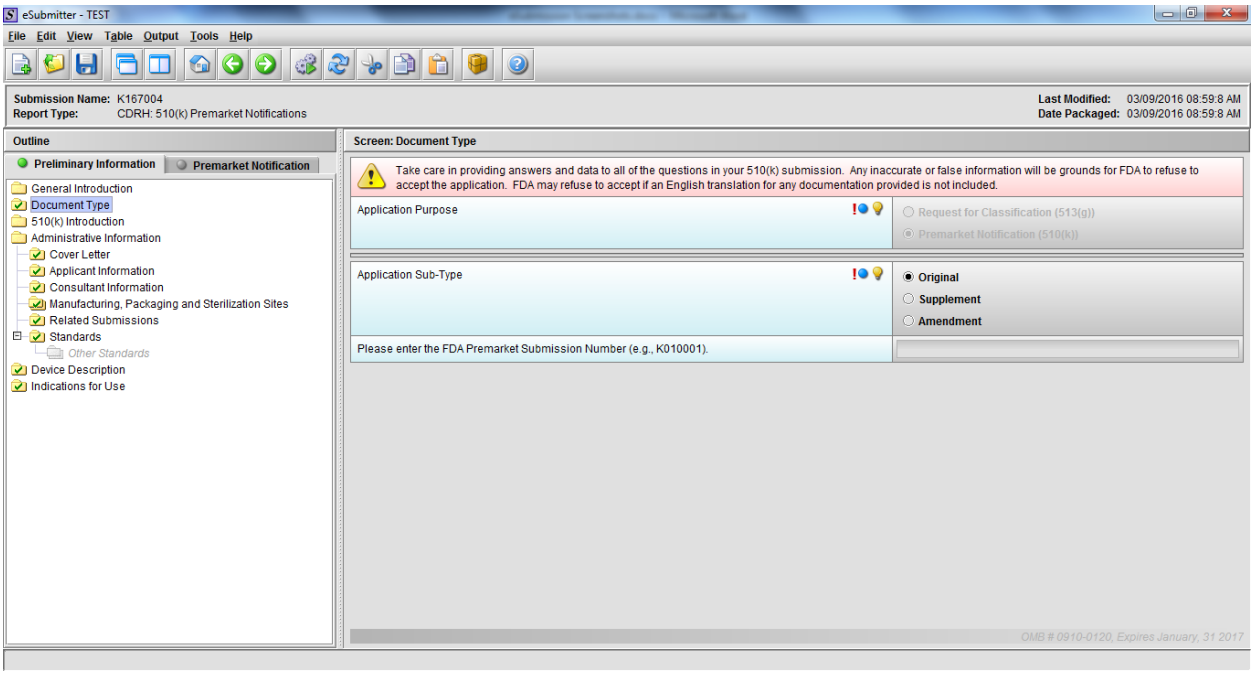
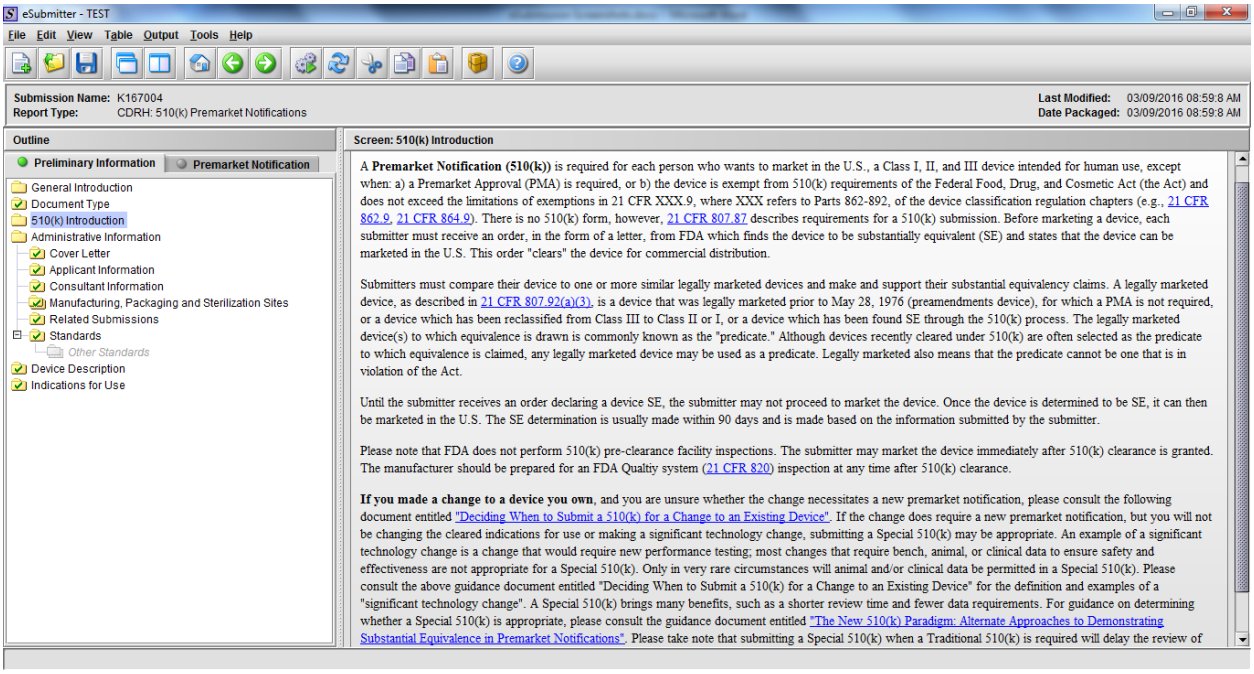
Note: Certain sections aren't needed depending on how certain questions are answered. For example, the sterilization section, biocompatibility section, software section, etc aren't necessary if the applicants indicate the device isn't sterilized, doesn't contact the patient, or doesn't use software, respectively. The Verification and Validation section on page 25 – 26 below is only needed for Special 510(k)s. Other sections will also not be required depending on how certain questions are answered (e.g., labeling, performance testing, clinical testing, etc).



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File Edit View Table Output Tools Help
Submission Name: K167004
Report Type: CDRH: 510(k) Premarket Notifications
Last Modified: 03/09/2016 08:59:8 AM
Date Packaged: 03/09/2016 08:59:8 AM
Outline
Preliminary Information
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Manufacturing, Packaging and Sterilization Sites
Related Submissions
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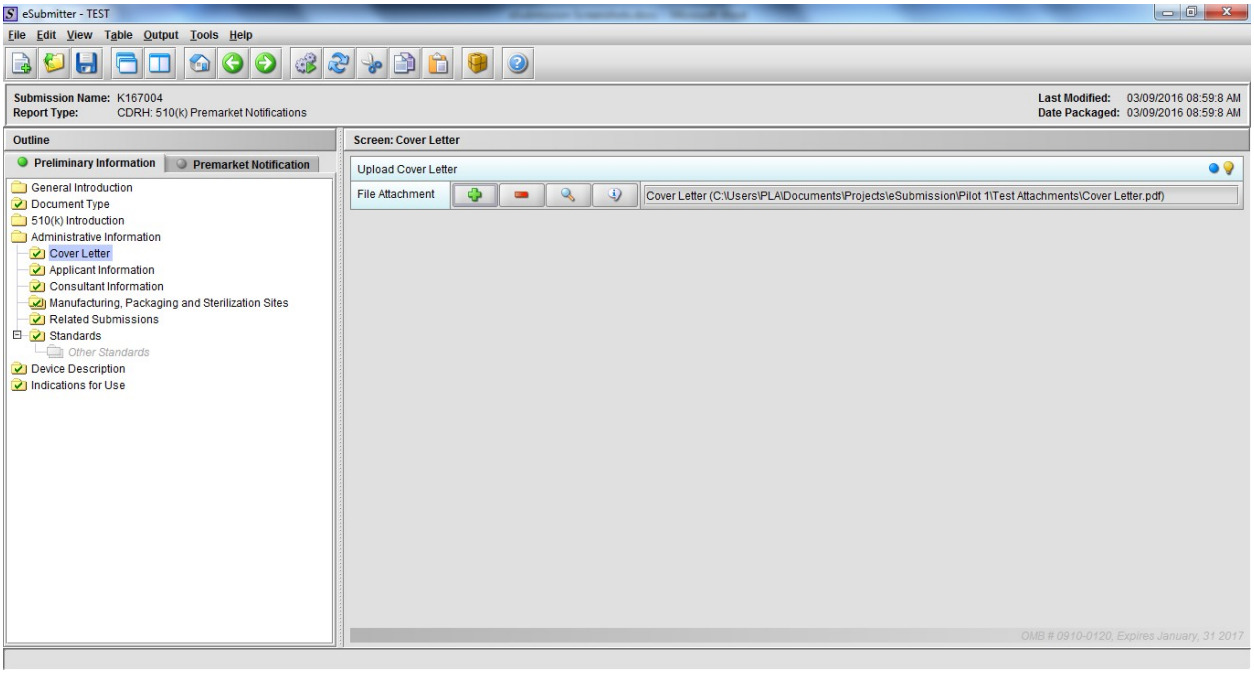
Other Standards
Device Description
Indications for Use
Screen: 510(k) Introduction
A Premarket Notification (510(k)) is required for each person who wants to market in the U.S., a Class I, II, and III device intended for human use, except when: a) a Premarket Approval (PMA) is required, or b) the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in 21 CFR XXX.9, where XXX refers to Parts 862-892, of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, 21 CFR 807.87 describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.
Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.
Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S. The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.
Please note that FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The manufacturer should be prepared for an FDA Quality system (21 CFR 820) inspection at any time after 510(k) clearance.
If you made a change to a device you own, and you are unsure whether the change necessitates a new premarket notification, please consult the following document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device". If the change does require a new premarket notification, but you will not be changing the cleared indications for use or making a significant technology change, submitting a Special 510(k) may be appropriate. An example of a significant technology change is a change that would require new performance testing; most changes that require bench, animal, or clinical data to ensure safety and effectiveness are not appropriate for a Special 510(k). Only in very rare circumstances will animal and/or clinical data be permitted in a Special 510(k). Please consult the above guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" for the definition and examples of a "significant technology change". A Special 510(k) brings many benefits, such as a shorter review time and fewer data requirements. For guidance on determining whether a Special 510(k) is appropriate, please consult the guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". Please take note that submitting a Special 510(k) when a Traditional 510(k) is required will delay the review of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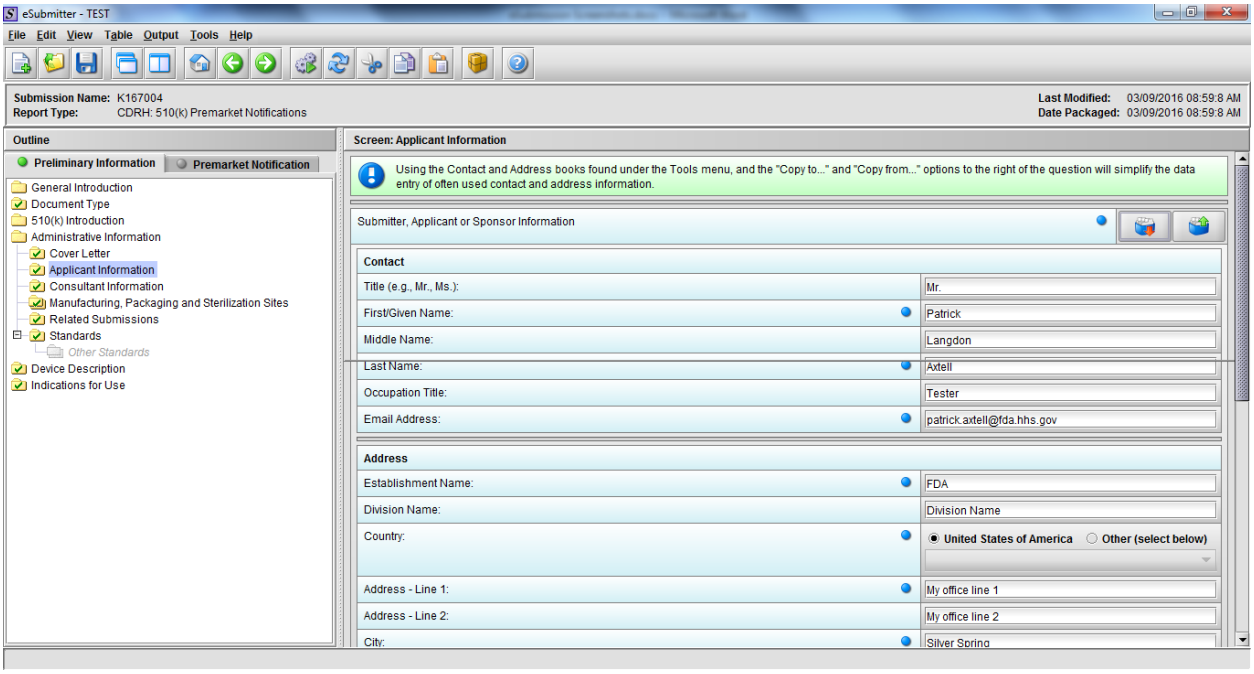
Screen: Cover Letter
Upload Cover Letter
File Attachment
Cover Letter (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Cover Letter.pdf)
OMB # 0910-0120, Expires January, 31 2017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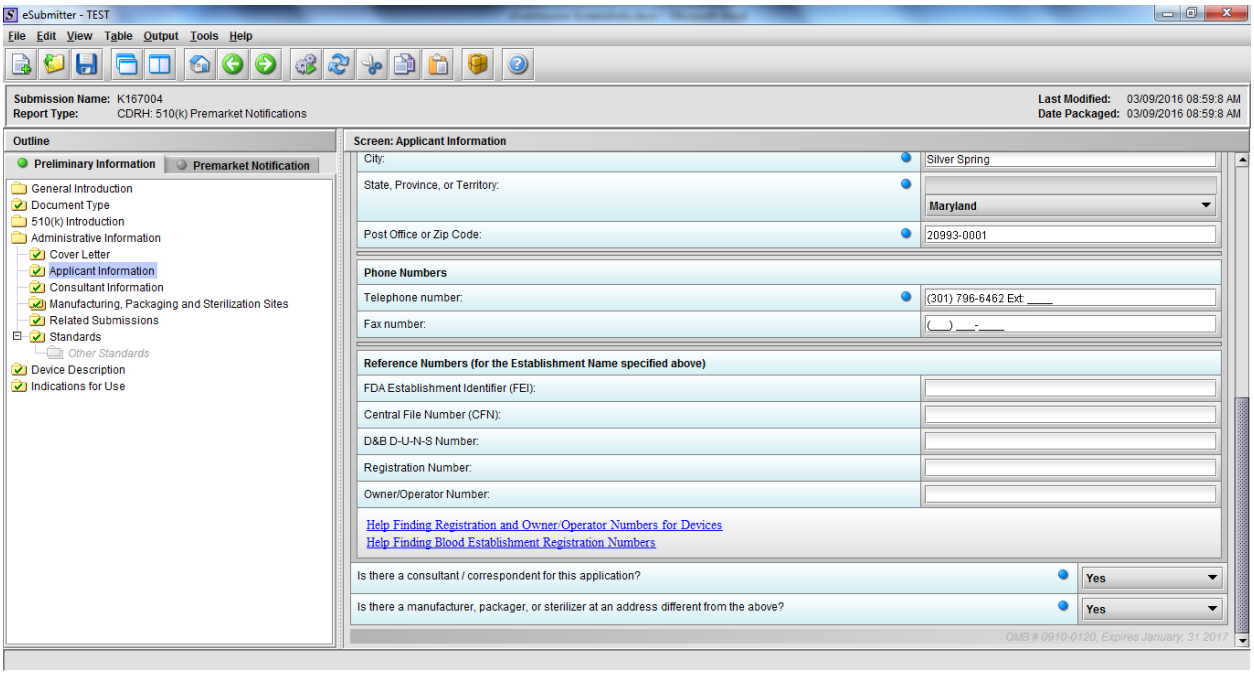
Screen: Applicant Information
Using the Contact and Address books found under the Tools menu, and the "Copy to..." and "Copy from..." options to the right of the question will simplify the data entry of often used contact and address information.
Submitter, Applicant or Sponsor Information
Contact
Title (e.g., Mr., Ms.):
Mr.
First/Given Name:
Patrick
Middle Name:
Langdon
Last Name:
Axtell
Occupation Title:
Tester
Email Address:
patrick.axtell@fda.hhs.gov
Address
Establishment Name:
FDA
Division Name:
Division Name
Country:
United States of America
Other (select below)
Address - Line 1:
My office line 1
Address - Line 2:
My office line 2
City:
Silver Spring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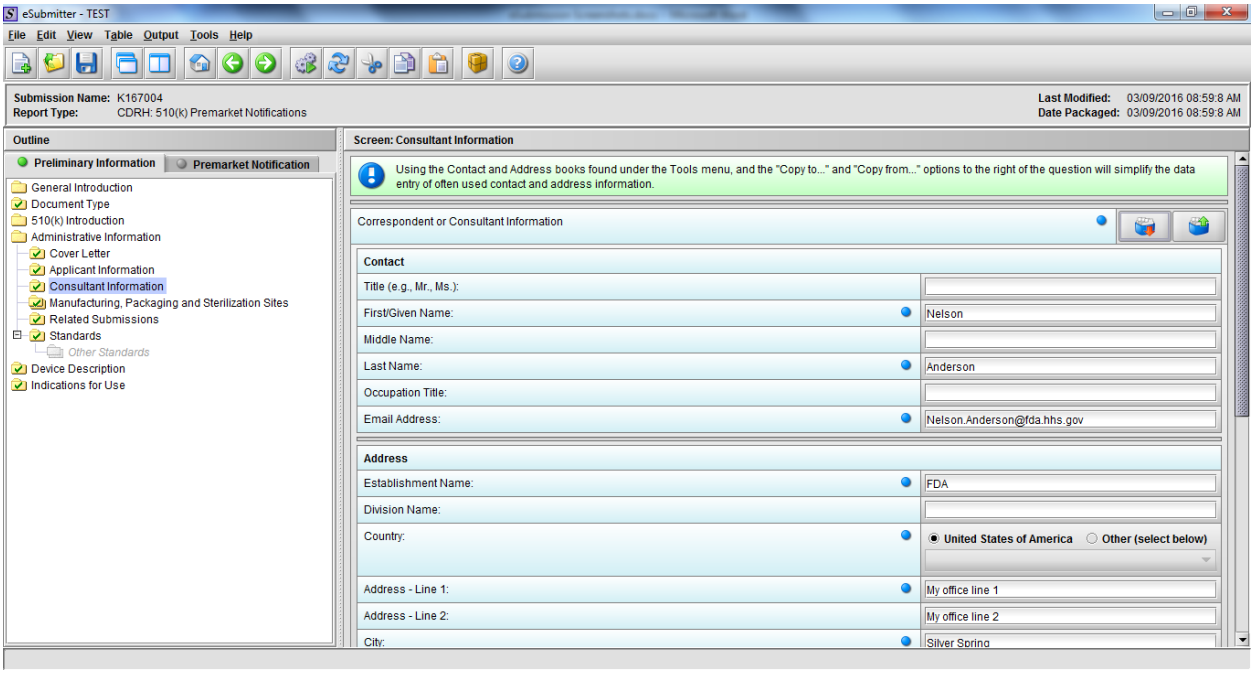
Preliminary Information
Premarket Notification
Screen: Applicant Information
City:
Silver Spring
State, Province, or Territory:
Maryland
Post Office or Zip Code:
20993-0001
Phone Numbers
Telephone number:
(301) 796-6462 Ext: ____
Fax number:
(___) ___-____
Reference Numbers (for the Establishment Name specified above)
FDA Establishment Identifier (FEI):
Central File Number (CFN):
D&B D-U-N-S Number:
Registration Number:
Owner/Operator Number:
Help Finding Registration and Owner/Operator Numbers for Devices
Help Finding Blood Establishment Registration Numbers
Is there a consultant / correspondent for this application?
Yes
Is there a manufacturer, packager, or sterilizer at an address different from the above?
Yes
OMB # 0910-0120, Expires January, 31 2017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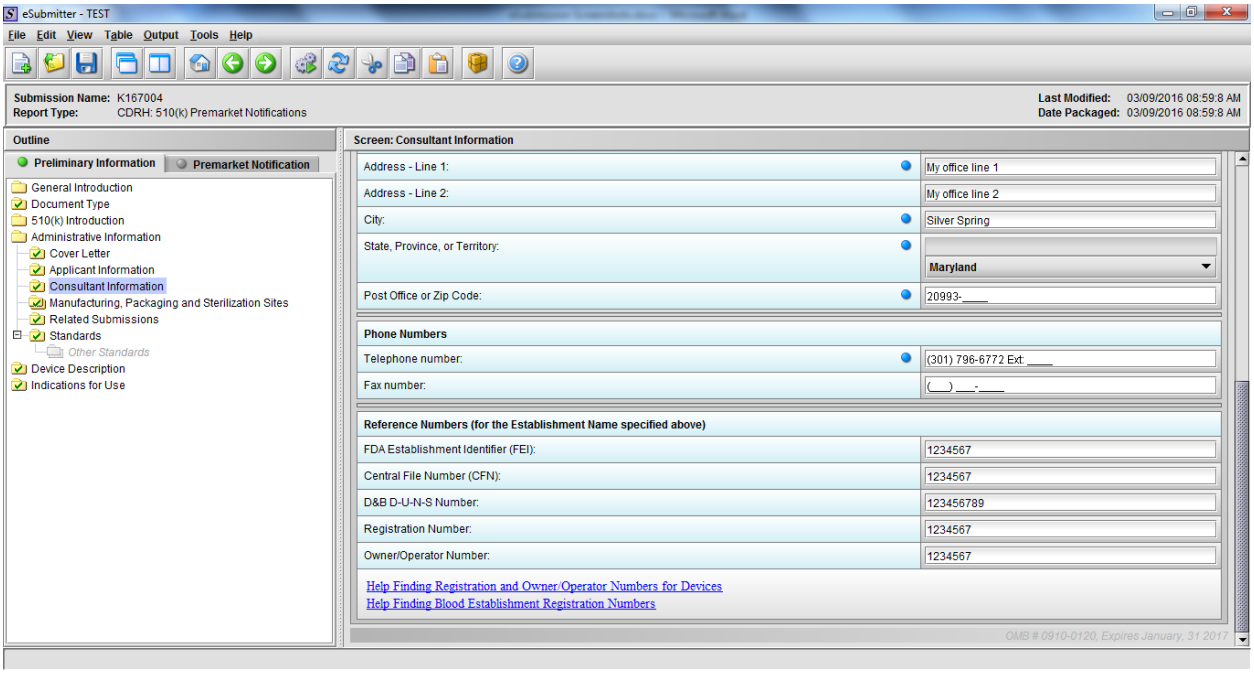
Indications for Use
Screen: Consultant Information
Using the Contact and Address books found under the Tools menu, and the "Copy to..." and "Copy from..." options to the right of the question will simplify the data entry of often used contact and address information.
Correspondent or Consultant Information
Contact
Title (e.g., Mr., Ms.):
First/Given Name: Nelson
Middle Name:
Last Name: Anderson
Occupation Title:
Email Address: Nelson.Anderson@fda.hhs.gov
Address
Establishment Name: FDA
Division Name:
Country: United States of America Other (select below)
Address - Line 1: My office line 1
Address - Line 2: My office line 2
City: Silver Spring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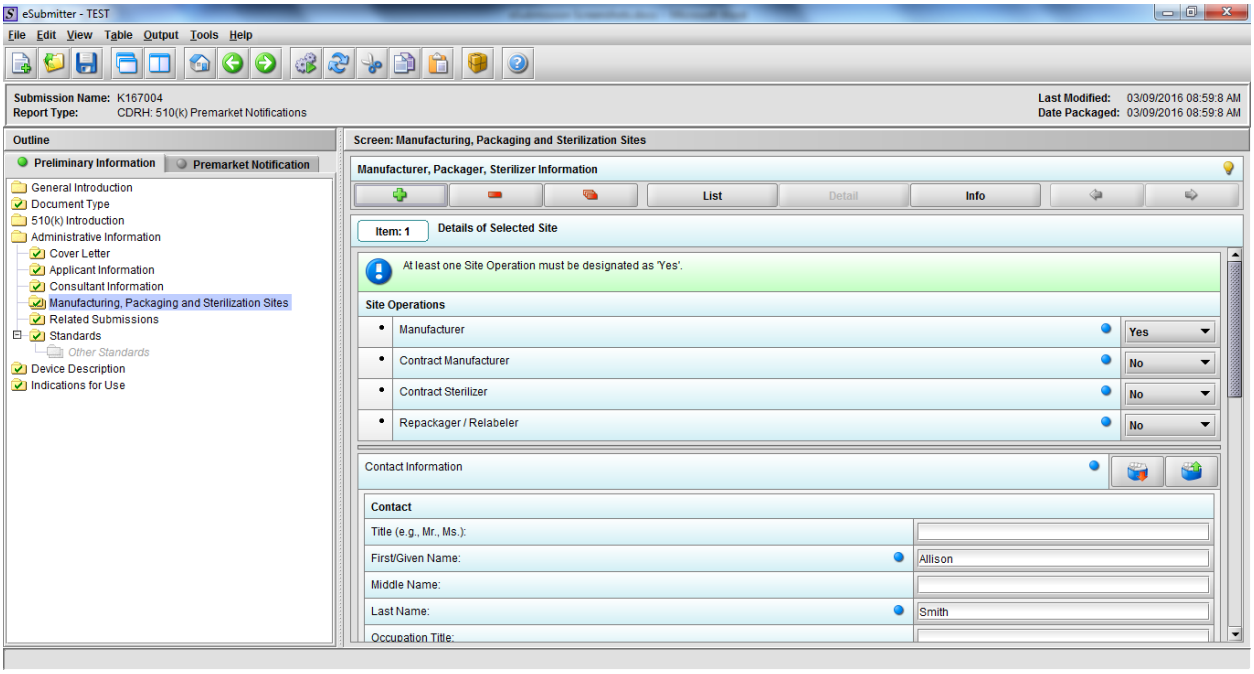
Device Description
Indications for Use
Screen: Consultant Information
Address - Line 1: My office line 1
Address - Line 2: My office line 2
City: Silver Spring
State, Province, or Territory: Maryland
Post Office or Zip Code: 20993-____
Phone Numbers
Telephone number: (301) 796-6772 Ext: ____
Fax number: (___) ___-____
Reference Numbers (for the Establishment Name specified above)
FDA Establishment Identifier (FEI): 1234567
Central File Number (CFN): 1234567
D&B D-U-N-S Number: 123456789
Registration Number: 1234567
Owner/Operator Number: 1234567
Help Finding Registration and Owner/Operator Numbers for Devices
Help Finding Blood Establishment Registration Numbers
OMB # 0910-0120, Expires January, 31 2017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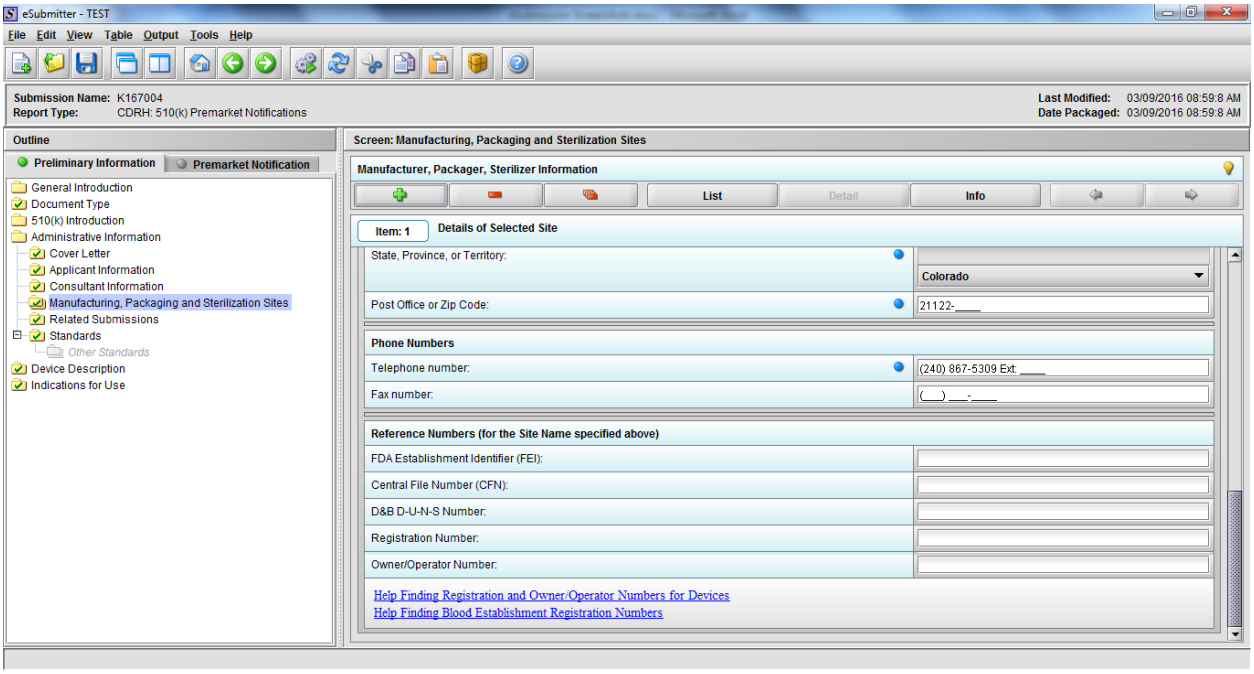
Screen: Manufacturing, Packaging and Sterilization Sites
Manufacturer, Packager, Sterilizer Information
List
Detail
Info
Item: 1
Details of Selected Site
At least one Site Operation must be designated as 'Yes'.
Site Operations
Manufacturer
Yes
Contract Manufacturer
No
Contract Sterilizer
No
Repackager / Relabeler
No
Contact Information
Contact
Title (e.g., Mr., Ms.):
First/Given Name:
Allison
Middle Name:
Last Name:
Smith
Occupation Title: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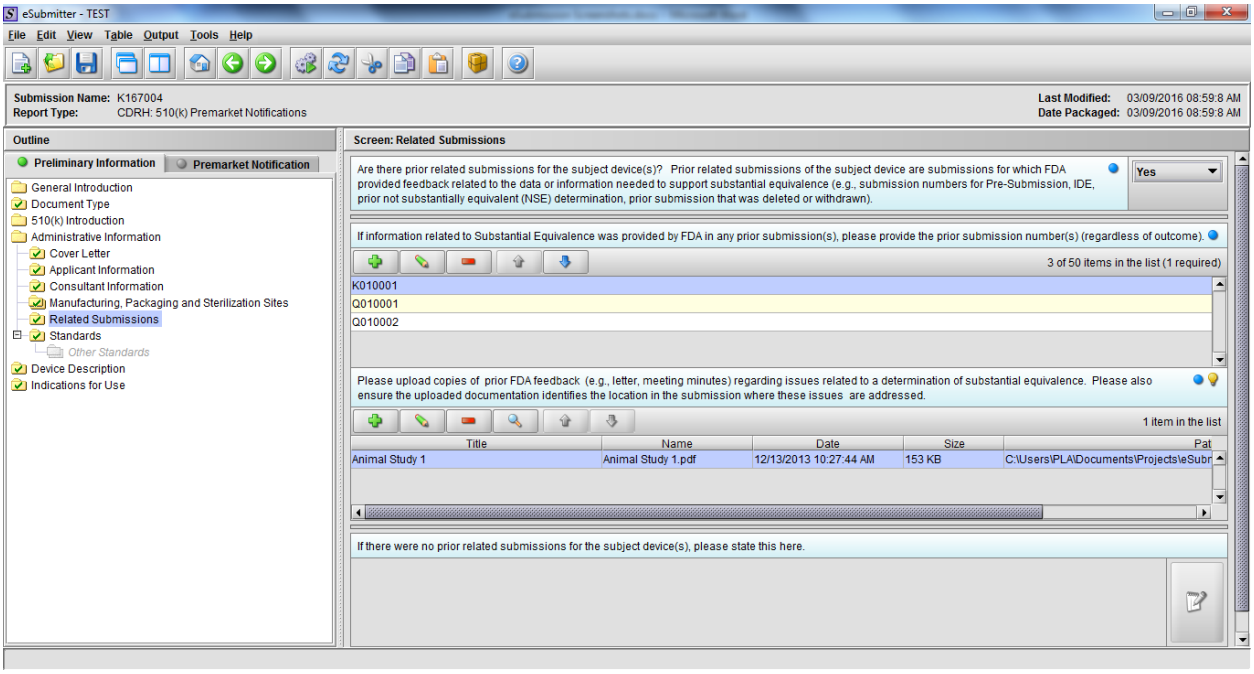
Indications for Use
Screen: Manufacturing, Packaging and Sterilization Sites
Manufacturer, Packager, Sterilizer Information
List
Detail
Info
Item: 1
Details of Selected Site
State, Province, or Territory:
Colorado
Post Office or Zip Code:
21122-____
Phone Numbers
Telephone number:
(240) 867-5309 Ext: ____
Fax number:
(___) ___-____
Reference Numbers (for the Site Name specified above)
FDA Establishment Identifier (FEI):
Central File Number (CFN):
D&B D-U-N-S Number:
Registration Number:
Owner/Operator Number:
Help Finding Registration and Owner/Operator Numbers for Devices
Help Finding Blood Establishment Registration Numbers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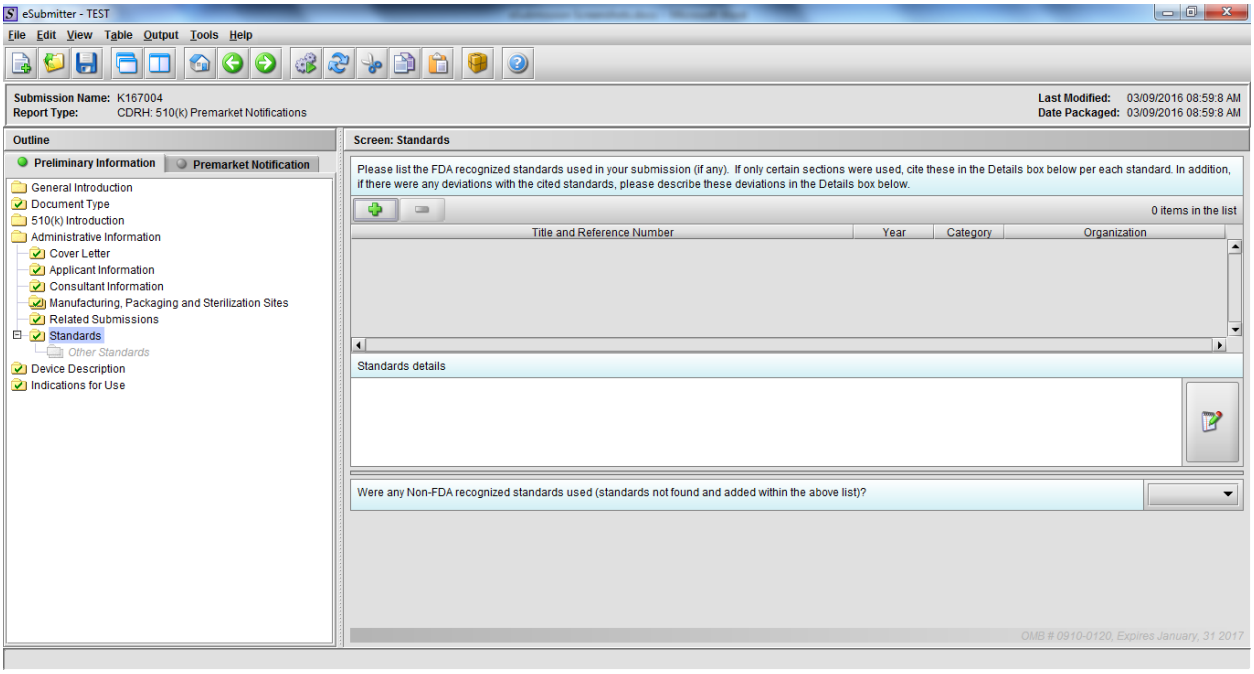
Screen: Related Submissions
Are there prior related submissions for the subject device(s)? Prior related submissions of the subject device are submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior submission that was deleted or withdrawn).
Yes
If information related to Substantial Equivalence was provided by FDA in any prior submission(s), please provide the prior submission number(s) (regardless of outcome).
3 of 50 items in the list (1 required)
K010001
Q010001
Q010002
Please upload copies of prior FDA feedback (e.g., letter, meeting minutes) regarding issues related to a determination of substantial equivalence. Please also ensure the uploaded documentation identifies the location in the submission where these issues are addressed.
1 item in the list
Title
Name
Date
Size
Pat
Animal Study 1
Animal Study 1.pdf
12/13/2013 10:27:44 AM
153 KB
C:\Users\PLA\Documents\Projects\eSubr
If there were no prior related submissions for the subject device(s), please state this here.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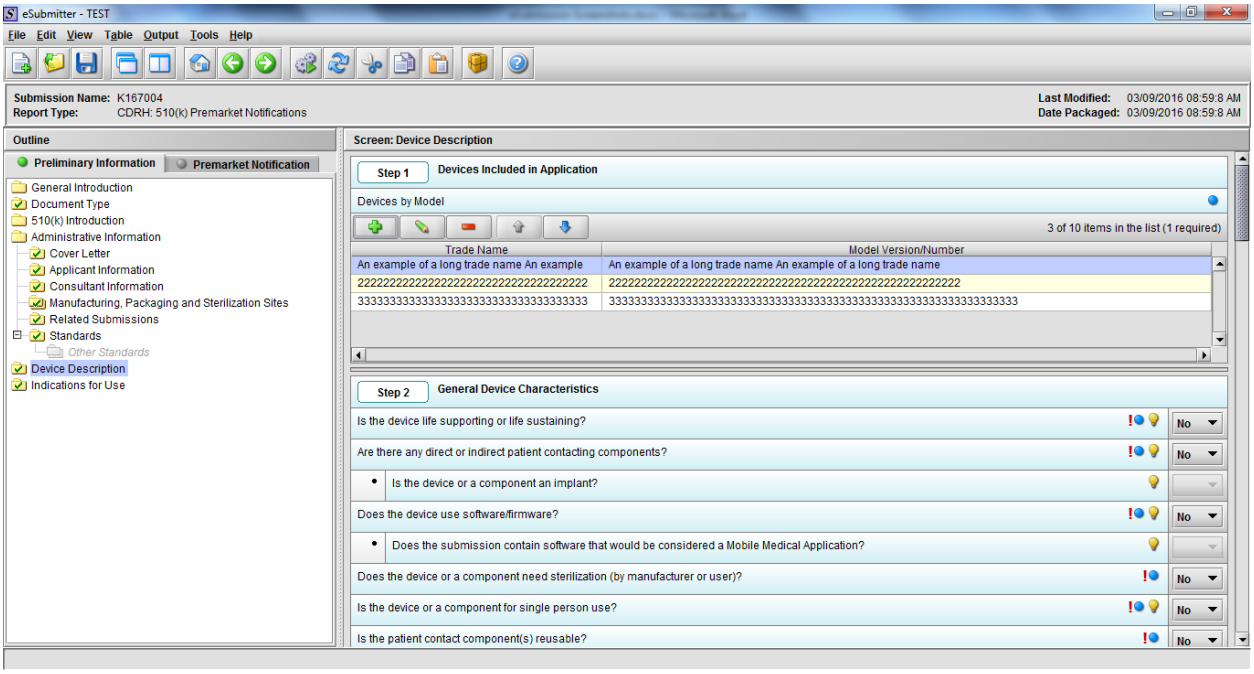
Screen: Standards
Please list the FDA recognized standards used in your submission (if any). If only certain sections were used, cite these in the Details box below per each standard. In addition, if there were any deviations with the cited standards, please describe these deviations in the Details box below.
0 items in the list
Title and Reference Number
Year
Category
Organization
Standards details
Were any Non-FDA recognized standards used (standards not found and added within the above list)?
OMB # 0910-0120, Expires January, 31 2017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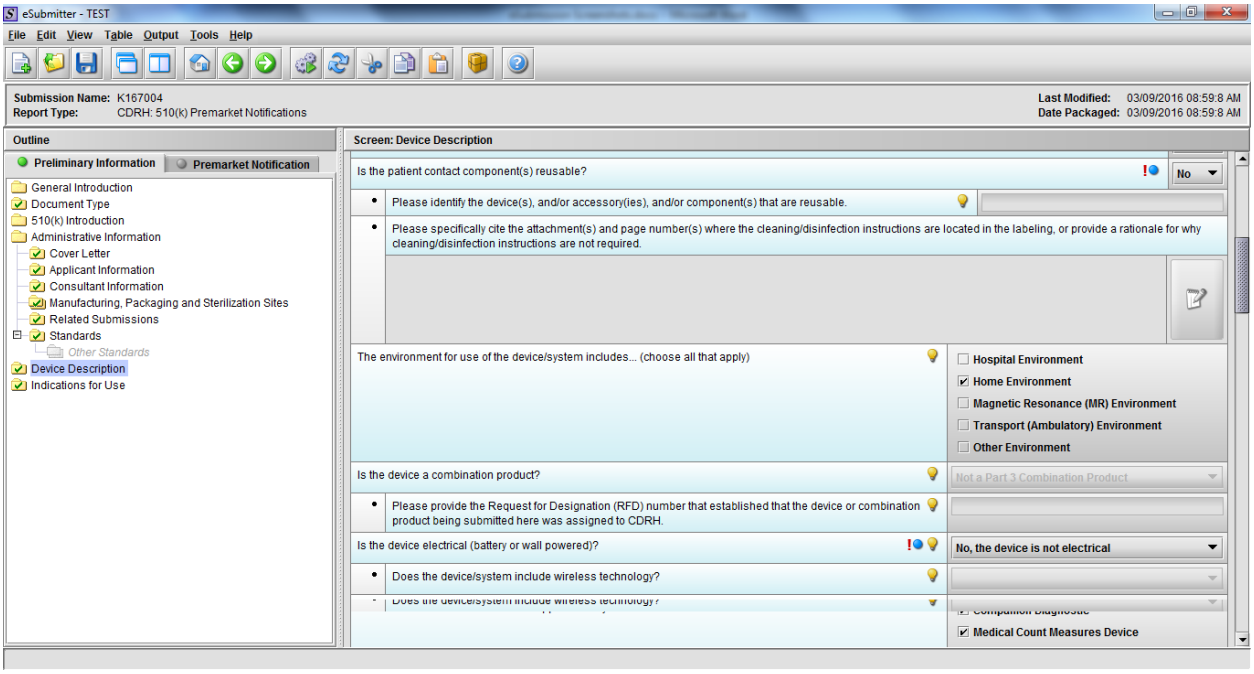
Step 1
Devices Included in Application
Devices by Model
3 of 10 items in the list (1 required)
Trade Name
Model Version/Number
An example of a long trade name An example
An example of a long trade name An example of a long trade name
Step 2
General Device Characteristics
Is the device life supporting or life sustaining?
No
Are there any direct or indirect patient contacting components?
No
Is the device or a component an implant?
Does the device use software/firmware?
No
Does the submission contain software that would be considered a Mobile Medical Application?
Does the device or a component need sterilization (by manufacturer or user)?
No
Is the device or a component for single person use?
No
Is the patient contact component(s) reusable?
No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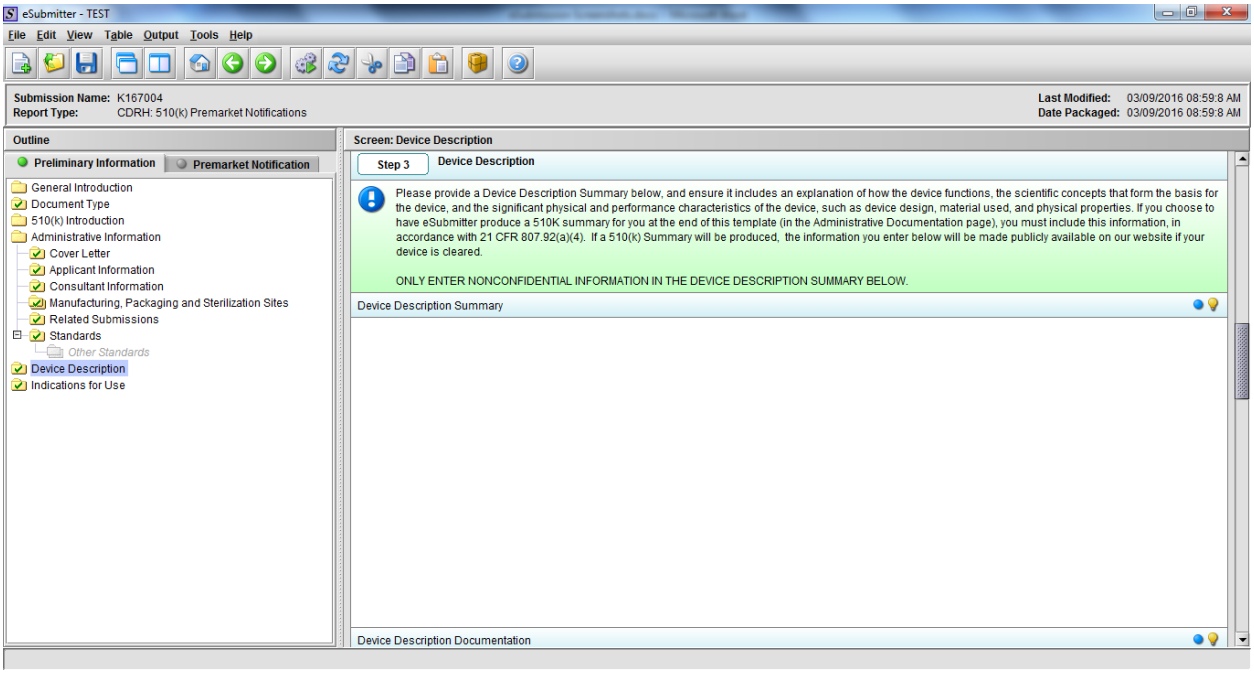
Is the patient contact component(s) reusable?
No
Please identify the device(s), and/or accessory(ies), and/or component(s) that are reusable.
Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling, or provide a rationale for why cleaning/disinfection instructions are not required.
The environment for use of the device/system includes... (choose all that apply)
Hospital Environment
Home Environment
Magnetic Resonance (MR) Environment
Transport (Ambulatory) Environment
Other Environment
Is the device a combination product?
Not a Part 3 Combination Product
Please provide the Request for Designation (RFD) number that established that the device or combination product being submitted here was assigned to CDRH.
Is the device electrical (battery or wall powered)?
No, the device is not electrical
Does the device/system include wireless technology?
Medical Count Measures Device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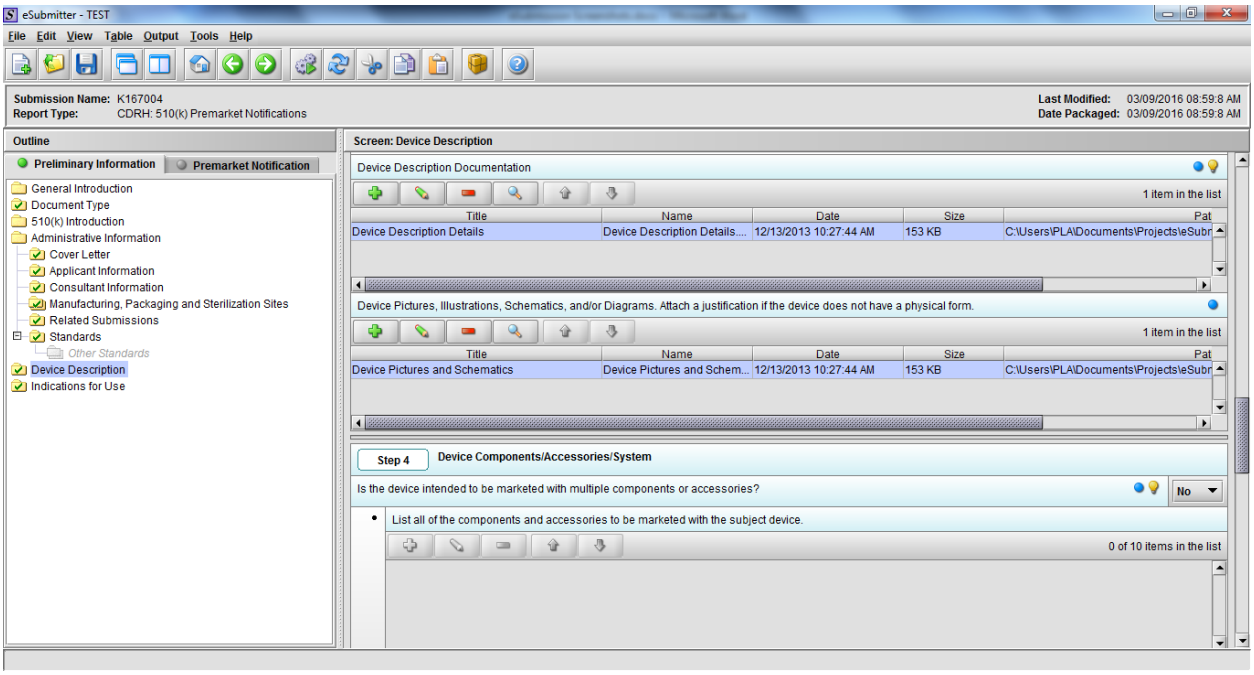
Screen: Device Description
Step 3
Device Description
Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties. If you choose to have eSubmitter produce a 510K summary for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(a)(4). If a 510(k) Summary will be produced, the information you enter below will be made publicly available on our website if your device is cleared.
ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY BELOW.
Device Description Summary
Device Description Documentation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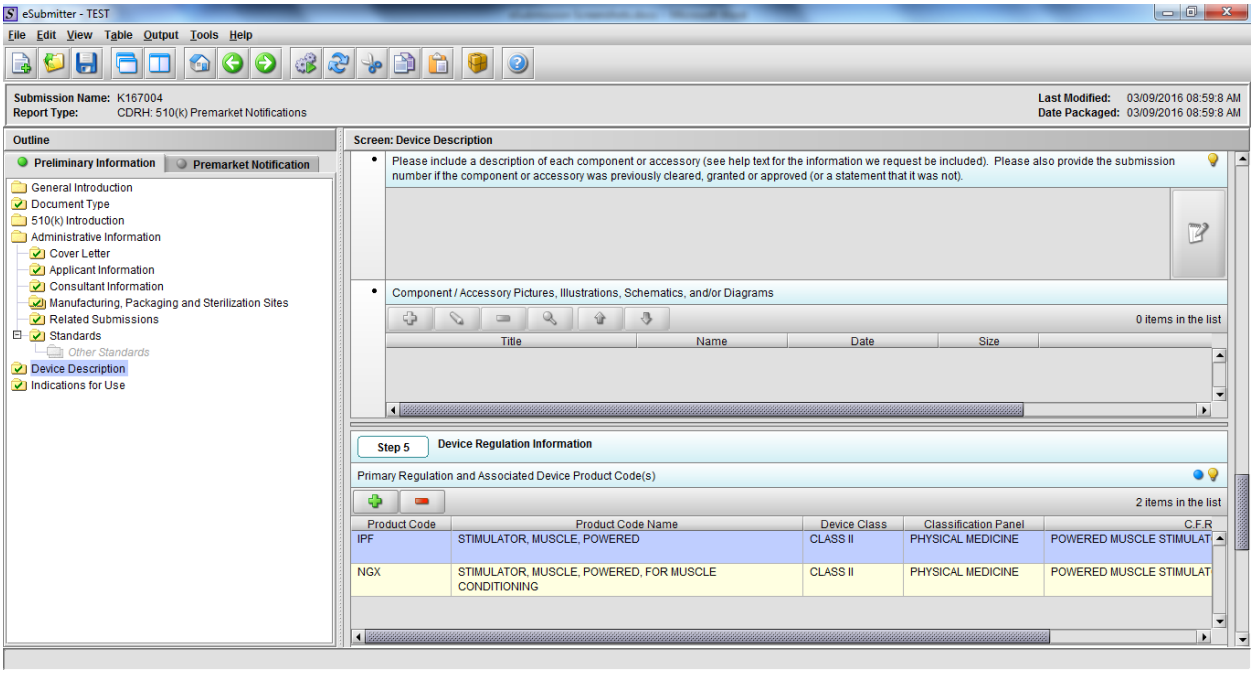
Screen: Device Description
Device Description Documentation
1 item in the list
Title
Name
Date
Size
Pat
Device Description Details
Device Description Details....
12/13/2013 10:27:44 AM
153 KB
C:\Users\PLA\Documents\Projects\eSubr
Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.
1 item in the list
Device Pictures and Schematics
Device Pictures and Schem...
12/13/2013 10:27:44 AM
153 KB
C:\Users\PLA\Documents\Projects\eSubr
Step 4
Device Components/Accessories/System
Is the device intended to be marketed with multiple components or accessories?
No
List all of the components and accessories to be marketed with the subject device.
0 of 10 items in the list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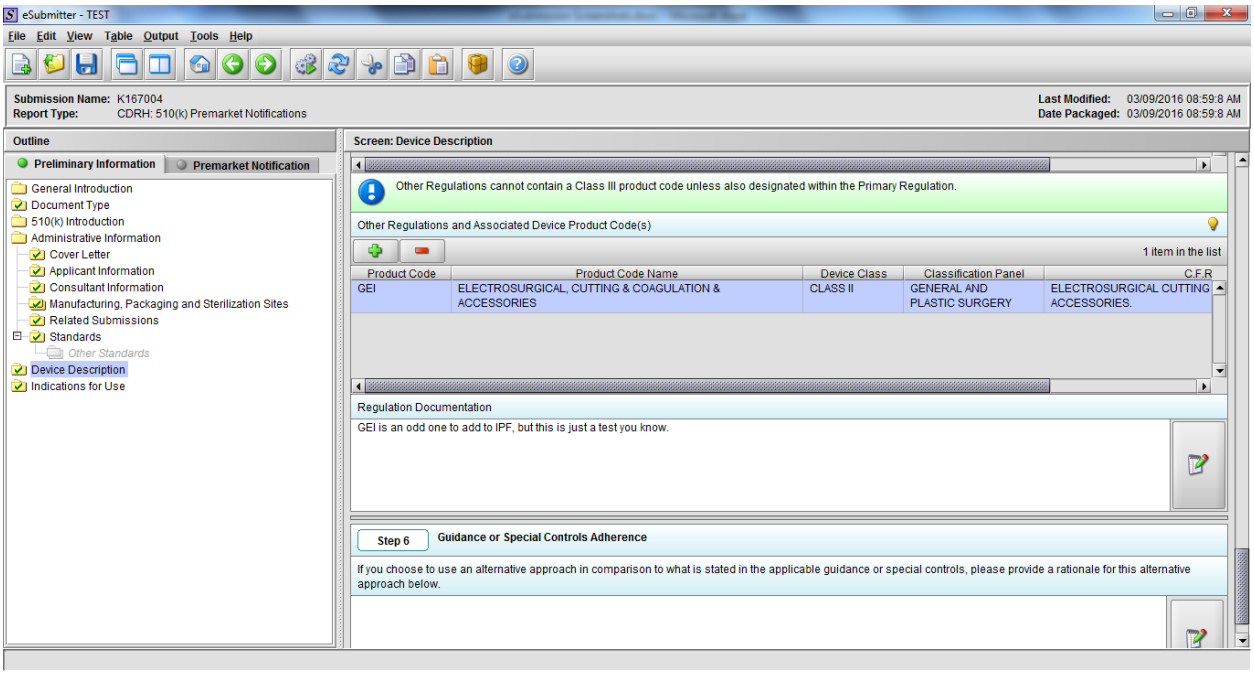
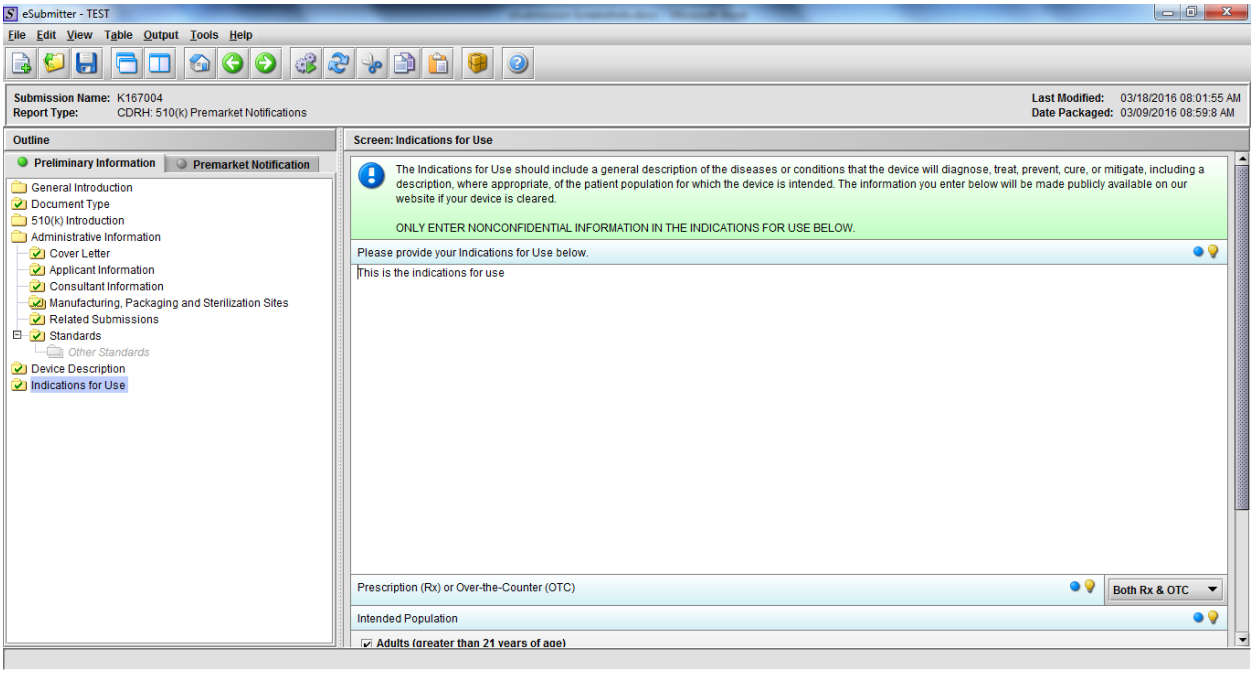
Please include a description of each component or accessory (see help text for the information we request be included). Please also provide the submission number if the component or accessory was previously cleared, granted or approved (or a statement that it was not).
Component / Accessory Pictures, Illustrations, Schematics, and/or Diagrams
0 items in the list
Title
Name
Date
Size
Step 5
Device Regulation Information
Primary Regulation and Associated Device Product Code(s)
2 items in the list
Product Code
Product Code Name
Device Class
Classification Panel
C.F.R
IPF
STIMULATOR, MUSCLE, POWERED
CLASS II
PHYSICAL MEDICINE
POWERED MUSCLE STIMULAT
NGX
STIMULATOR, MUSCLE, POWERED, FOR MUSCLE CONDITIONING
CLASS II
PHYSICAL MEDICINE
POWERED MUSCLE STIMULAT


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: K167004
Report Type: CDRH: 510(k) Premarket Notifications
Last Modified: 03/09/2016 08:59:8 AM
Date Packaged: 03/09/2016 08:59:8 AM
Outline
Preliminary Information
Premarket Notification
General Introduction
Document Type
510(k) Introduction
Administrative Information
Cover Letter
Applicant Information
Consultant Information
Manufacturing, Packaging and Sterilization Sites
Related Submissions
Standards
Other Standards
Device Description
Indications for Use
Screen: Device Description
Other Regulations cannot contain a Class III product code unless also designated within the Primary Regulation.
Other Regulations and Associated Device Product Code(s)
1 item in the list
Product Code
Product Code Name
Device Class
Classification Panel
C.F.R
GEI
ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES
CLASS II
GENERAL AND PLASTIC SURGERY
ELECTROSURGICAL CUTTING ACCESSORIES.
Regulation Documentation
GEI is an odd one to add to IPF, but this is just a test you know.
Step 6
Guidance or Special Controls Adherence
If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.


eSubmitter - TEST
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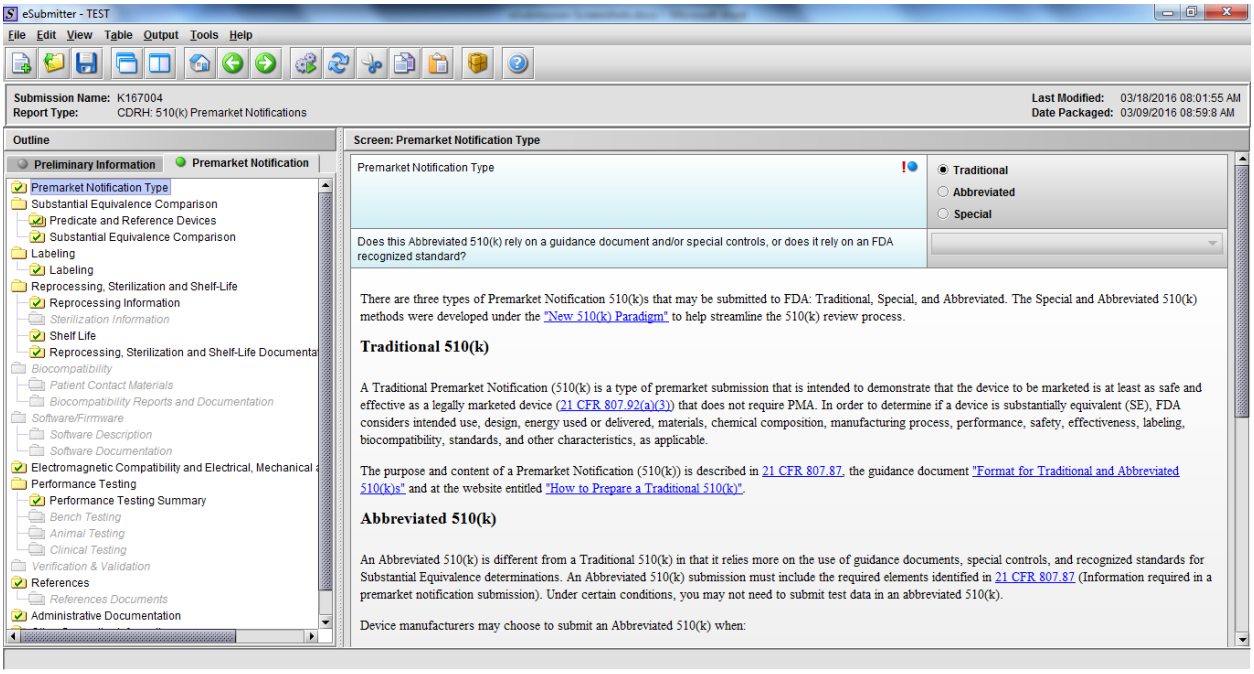
Related Submissions
Standards
Other Standards
Device Description
Indications for Use
Screen: Indications for Use
The Indications for Use should include a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. The information you enter below will be made publicly available on our website if your device is cleared.
ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE INDICATIONS FOR USE BELOW.
Please provide your Indications for Use below.
This is the indications for use
Prescription (Rx) or Over-the-Counter (OTC)
Both Rx & OTC
Intended Population
Adults (greater than 21 years of age)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Substantial Equivalence Comparison
Predicate and Reference Devices
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Sterilization Information
Shelf Life
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Biocompatibility
Patient Contact Materials
Biocompatibility Reports and Documentation
Software/Firmware
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Software Documentation
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Performance Testing
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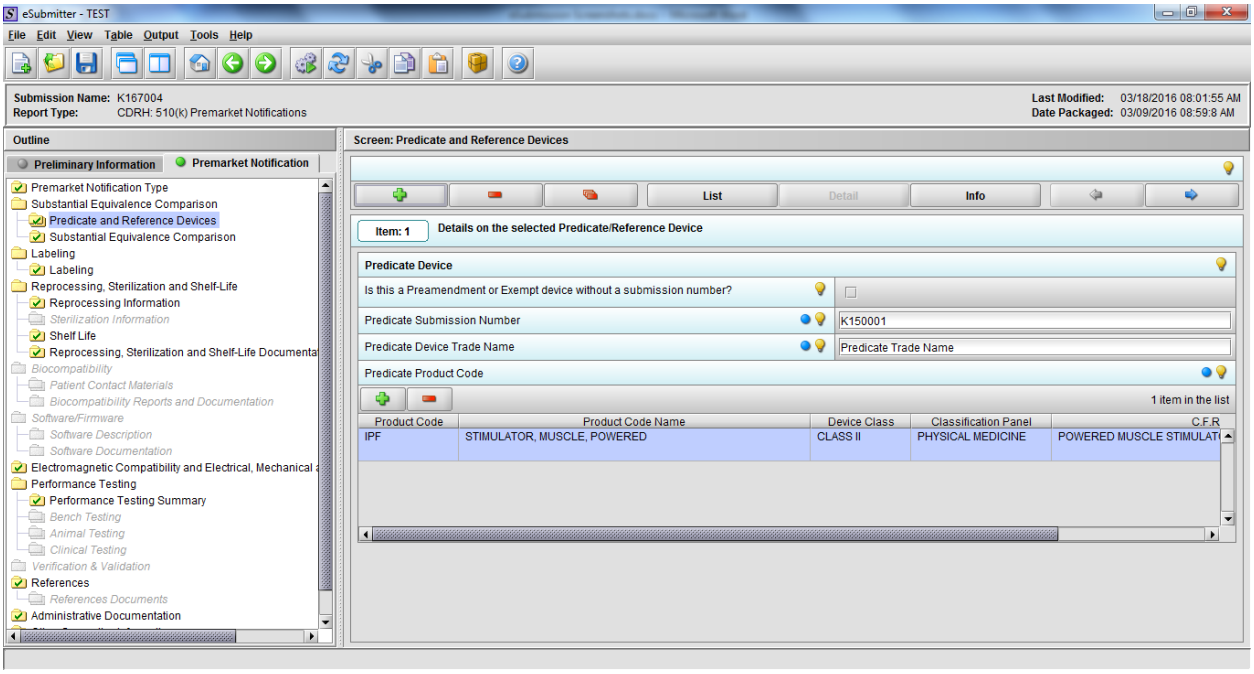
References
References Documents
Administrative Documentation
Screen: Premarket Notification Type
Premarket Notification Type
Traditional
Abbreviated
Special
Does this Abbreviated 510(k) rely on a guidance document and/or special controls, or does it rely on an FDA recognized standard?
There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under the "New 510(k) Paradigm" to help streamline the 510(k) review process.
Traditional 510(k)
A Traditional Premarket Notification (510(k) is a type of premarket submission that is intended to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device (21 CFR 807.92(a)(3)) that does not require PMA. In order to determine if a device is substantially equivalent (SE), FDA considers intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.
The purpose and content of a Premarket Notification (510(k)) is described in 21 CFR 807.87, the guidance document "Format for Traditional and Abbreviated 510(k)s" and at the website entitled "How to Prepare a Traditional 510(k)".
Abbreviated 510(k)
An Abbreviated 510(k) is different from a Traditional 510(k) in that it relies more on the use of guidance documents, special controls, and recognized standards for Substantial Equivalence determinations. An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87 (Information required in a premarket notification submission). Under certain conditions, you may not need to submit test data in an abbreviated 510(k).
Device manufacturers may choose to submit an Abbreviated 510(k) when: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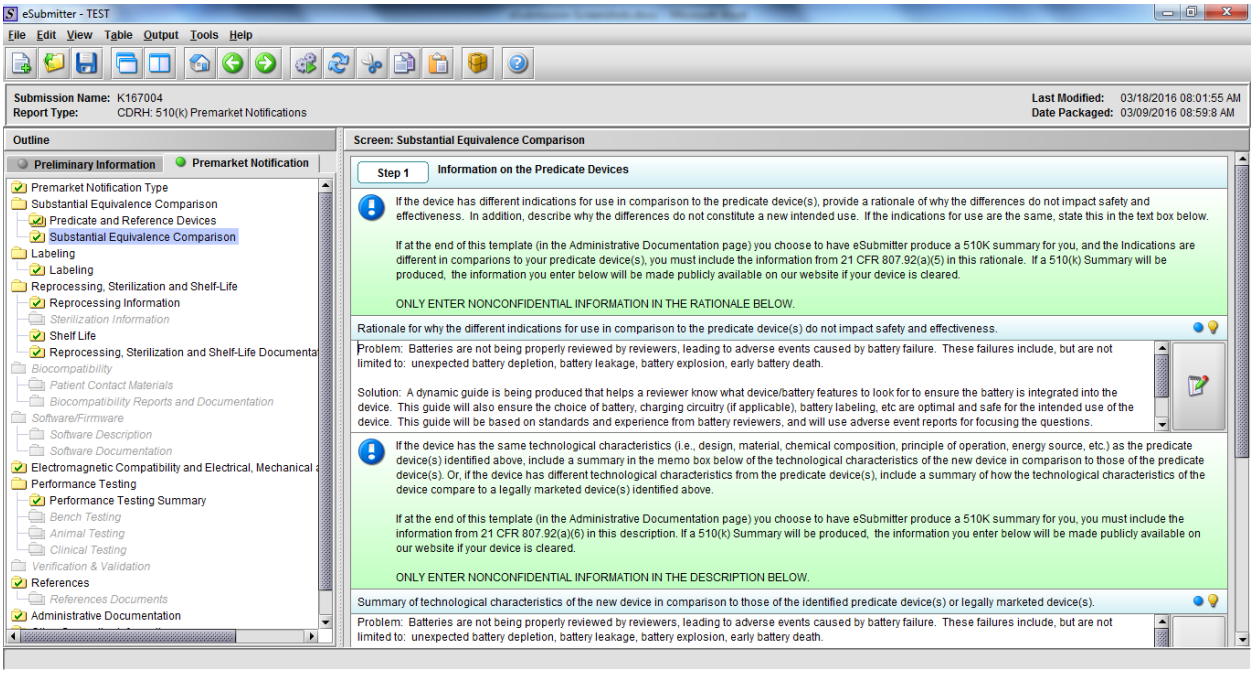
Screen: Predicate and Reference Devices
List
Detail
Info
Item: 1
Details on the selected Predicate/Reference Device
Predicate Device
Is this a Preamendment or Exempt device without a submission number?
Predicate Submission Number
K150001
Predicate Device Trade Name
Predicate Trade Name
Predicate Product Code
1 item in the list
Product Code
Product Code Name
Device Class
Classification Panel
C.F.R
IPF
STIMULATOR, MUSCLE, POWERED
CLASS II
PHYSICAL MEDICINE
POWERED MUSCLE STIMULAT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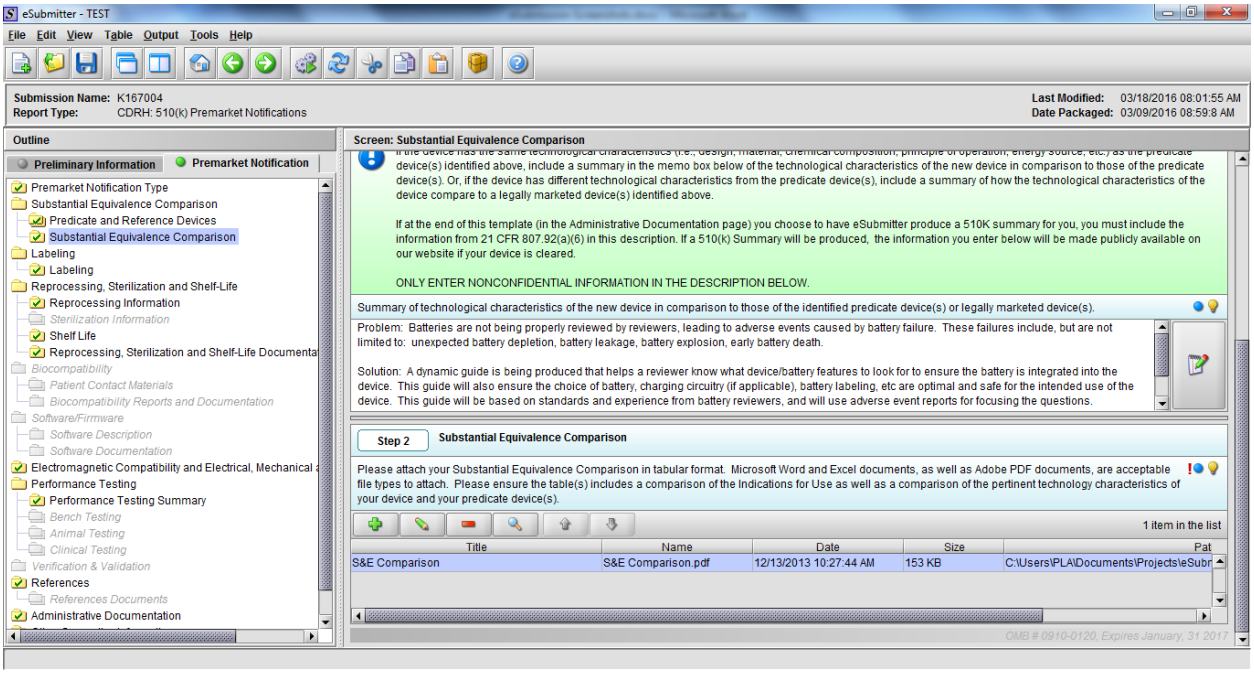
Screen: Substantial Equivalence Comparison
Step 1
Information on the Predicate Devices
If the device has different indications for use in comparison to the predicate device(s), provide a rationale of why the differences do not impact safety and effectiveness. In addition, describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.
If at the end of this template (in the Administrative Documentation page) you choose to have eSubmitter produce a 510K summary for you, and the Indications are different in comparions to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. If a 510(k) Summary will be produced, the information you enter below will be made publicly available on our website if your device is cleared.
ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE BELOW.
Rationale for why the different indications for use in comparison to the predicate device(s) do not impact safety and effectiveness.
Problem: Batteries are not being properly reviewed by reviewers, leading to adverse events caused by battery failure. These failures include, but are not limited to: unexpected battery depletion, battery leakage, battery explosion, early battery death.
Solution: A dynamic guide is being produced that helps a reviewer know what device/battery features to look for to ensure the battery is integrated into the device. This guide will also ensure the choice of battery, charging circuitry (if applicable), battery labeling, etc are optimal and safe for the intended use of the device. This guide will be based on standards and experience from battery reviewers, and will use adverse event reports for focusing the questions.
If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.
If at the end of this template (in the Administrative Documentation page) you choose to have eSubmitter produce a 510K summary for you, you must include the information from 21 CFR 807.92(a)(6) in this description. If a 510(k) Summary will be produced, the information you enter below will be made publicly available on our website if your device is cleared.
ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION BELOW.
Summary of technological characteristics of the new device in comparison to those of the identified predicate device(s) or legally marketed device(s).
Problem: Batteries are not being properly reviewed by reviewers, leading to adverse events caused by battery failure. These failures include, but are not limited to: unexpected battery depletion, battery leakage, battery explosion, early battery death.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Performance Testing
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Clinical Testing
Verification & Validation
References
References Documents
Administrative Documentation
Screen: Substantial Equivalence Comparison
device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.
If at the end of this template (in the Administrative Documentation page) you choose to have eSubmitter produce a 510K summary for you, you must include the information from 21 CFR 807.92(a)(6) in this description. If a 510(k) Summary will be produced, the information you enter below will be made publicly available on our website if your device is cleared.
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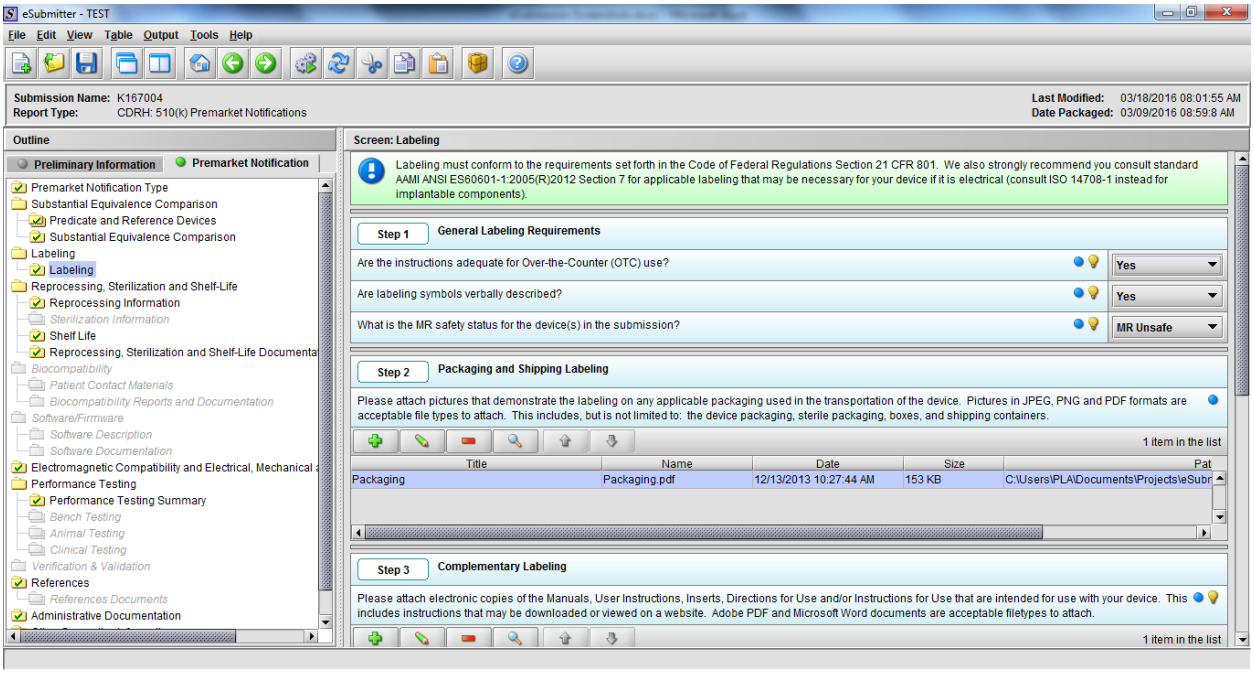
Solution: A dynamic guide is being produced that helps a reviewer know what device/battery features to look for to ensure the battery is integrated into the device. This guide will also ensure the choice of battery, charging circuitry (if applicable), battery labeling, etc are optimal and safe for the intended use of the device. This guide will be based on standards and experience from battery reviewers, and will use adverse event reports for focusing the questions.
Step 2
Substantial Equivalence Comparison
Please attach your Substantial Equivalence Comparison in tabular format. Microsoft Word and Excel documents, as well as Adobe PDF documents, are acceptable file types to attach. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s).
1 item in the list
Title
Name
Date
Size
Pat
S&E Comparison
S&E Comparison.pdf
12/13/2013 10:27:44 AM
153 KB
C:\Users\PLA\Documents\Projects\eSubr
OMB # 0910-0120, Expires January, 31 2017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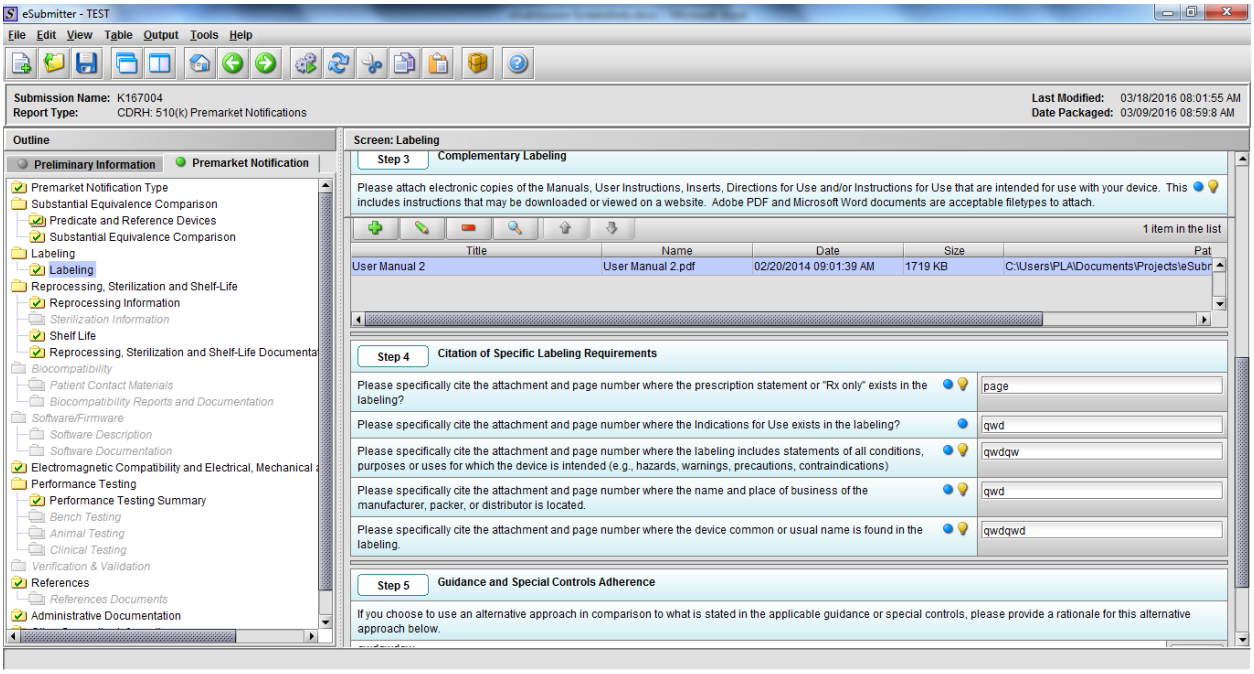
Screen: Labeling
Labeling must conform to the requirements set forth in the Code of Federal Regulations Section 21 CFR 801. We also strongly recommend you consult standard AAMI ANSI ES60601-1:2005(R)2012 Section 7 for applicable labeling that may be necessary for your device if it is electrical (consult ISO 14708-1 instead for implantable components).
Step 1
General Labeling Requirements
Are the instructions adequate for Over-the-Counter (OTC) use?
Yes
Are labeling symbols verbally described?
Yes
What is the MR safety status for the device(s) in the submission?
MR Unsafe
Step 2
Packaging and Shipping Labeling
Please attach pictures that demonstrate the labeling on any applicable packaging used in the transportation of the device. Pictures in JPEG, PNG and PDF formats are acceptable file types to attach. This includes, but is not limited to: the device packaging, sterile packaging, boxes, and shipping containers.
1 item in the list
Title
Name
Date
Size
Pat
Packaging
Packaging.pdf
12/13/2013 10:27:44 AM
153 KB
C:\Users\PLA\Documents\Projects\eSubr
Step 3
Complementary Labeling
Please attach electronic copies of the Manuals, User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website. Adobe PDF and Microsoft Word documents are acceptable filetypes to attach.
1 item in the list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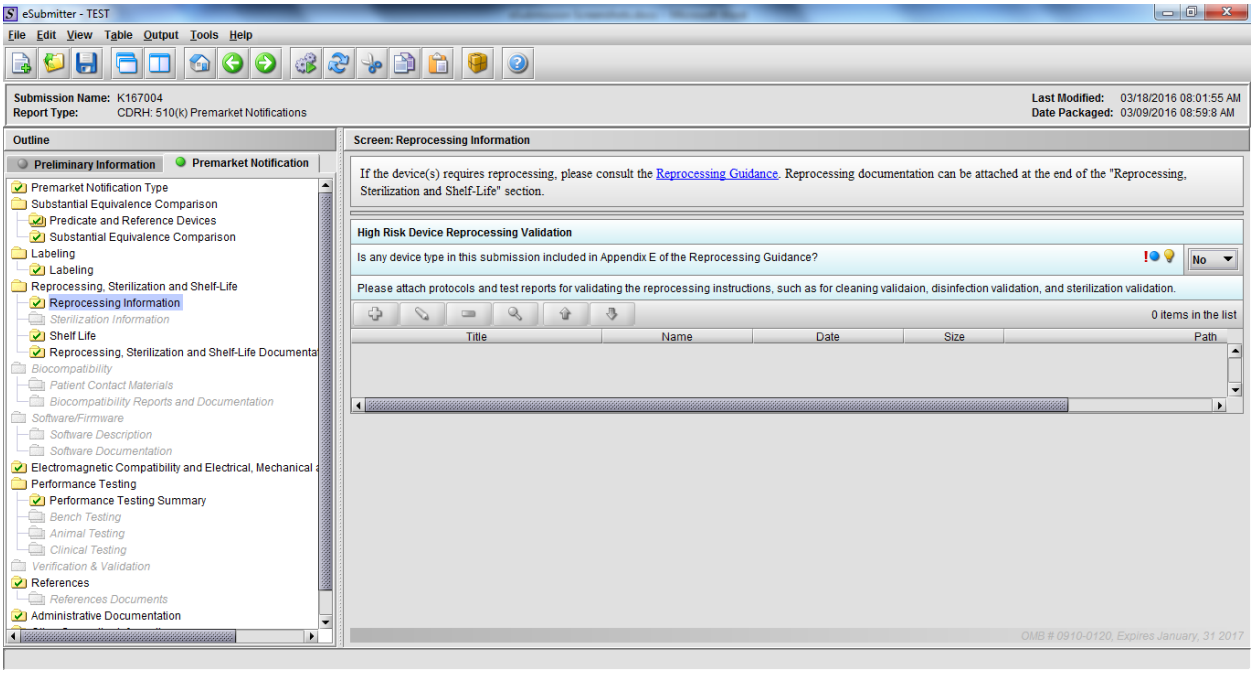
1 item in the list
Title
Name
Date
Size
Pat
User Manual 2
User Manual 2.pdf
02/20/2014 09:01:39 AM
1719 KB
C:\Users\PLA\Documents\Projects\eSubr
Step 4
Citation of Specific Labeling Requirements
Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling?
page
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling?
qwd
Please specifically cite the attachment and page number where the labeling includes statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications)
qwdqw
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.
qwd
Please specifically cite the attachment and page number where the device common or usual name is found in the labeling.
qwdqwd
Step 5
Guidance and Special Controls Adherence
If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.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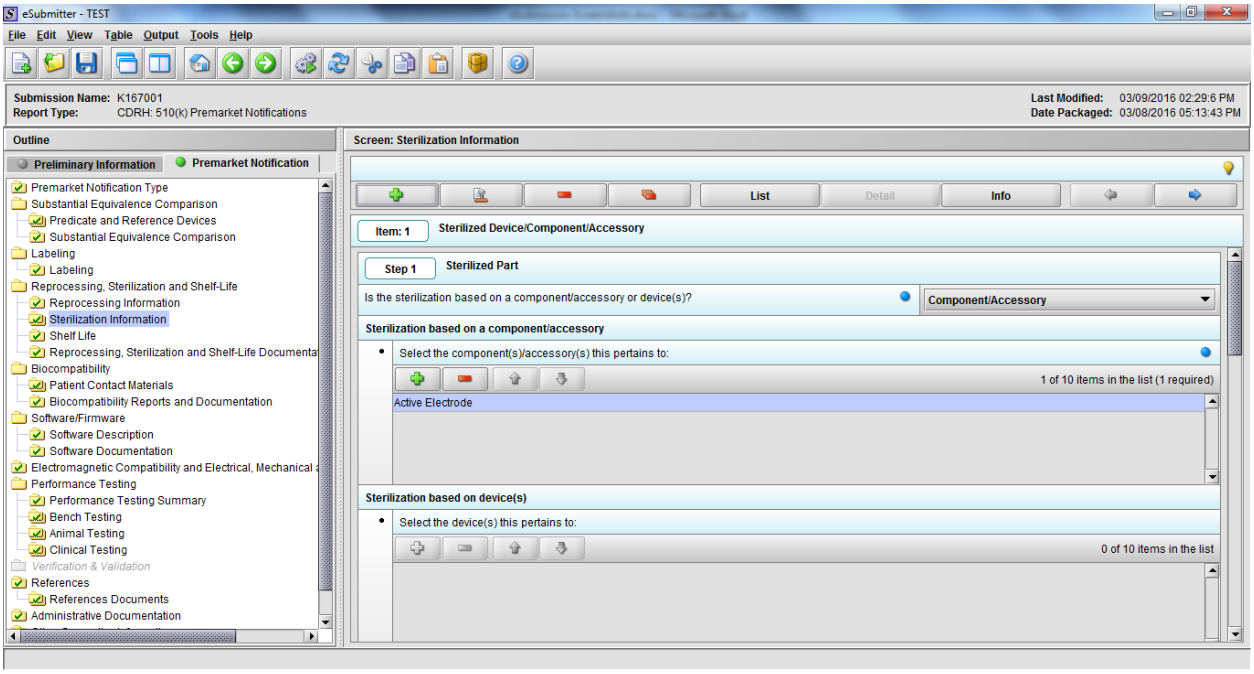
Screen: Reprocessing Information
If the device(s) requires reprocessing, please consult the Reprocessing Guidance. Reprocessing documentation can be attached at the end of the "Reprocessing, Sterilization and Shelf-Life" section.
High Risk Device Reprocessing Validation
Is any device type in this submission included in Appendix E of the Reprocessing Guidance?
No
Please attach protocols and test reports for validating the reprocessing instructions, such as for cleaning validaion, disinfection validation, and sterilization validation.
0 items in the list
Title
Name
Date
Size
Path
OMB # 0910-0120, Expires January, 31 2017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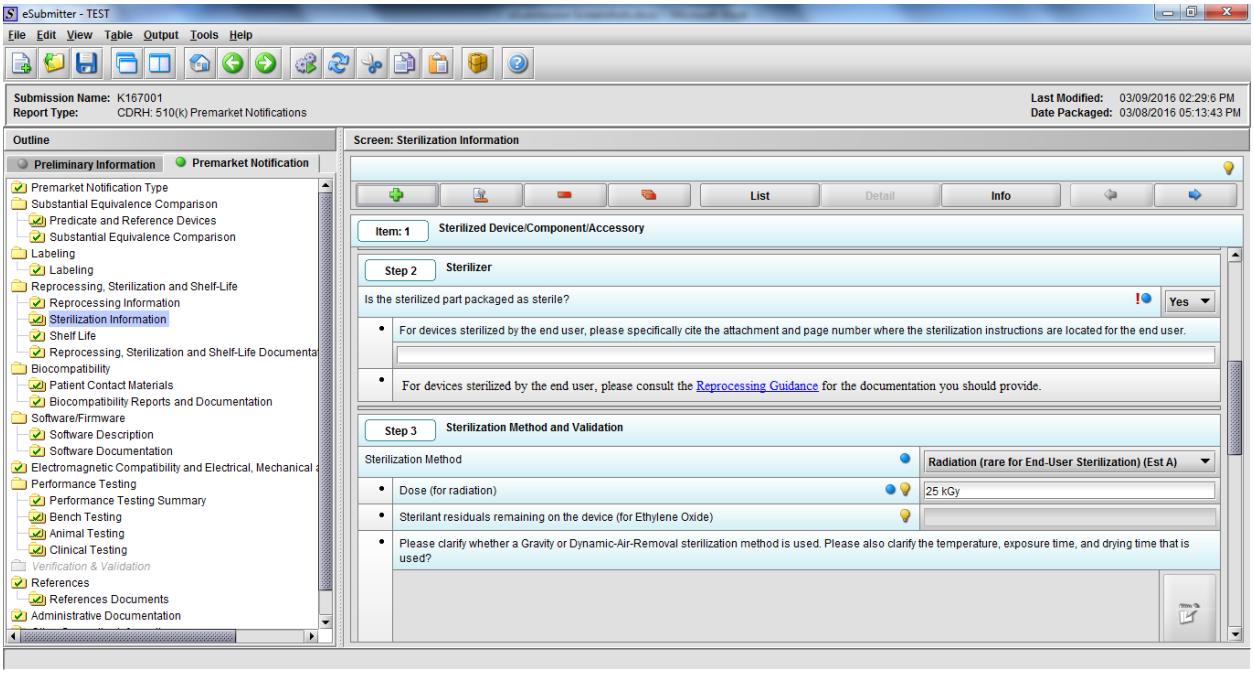
Screen: Sterilization Information
List
Detail
Info
Item: 1
Sterilized Device/Component/Accessory
Step 1
Sterilized Part
Is the sterilization based on a component/accessory or device(s)?
Component/Accessory
Sterilization based on a component/accessory
Select the component(s)/accessory(s) this pertains to:
1 of 10 items in the list (1 required)
Active Electrode
Sterilization based on device(s)
Select the device(s) this pertains to:
0 of 10 items in the list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Screen: Sterilization Information
List
Detail
Info
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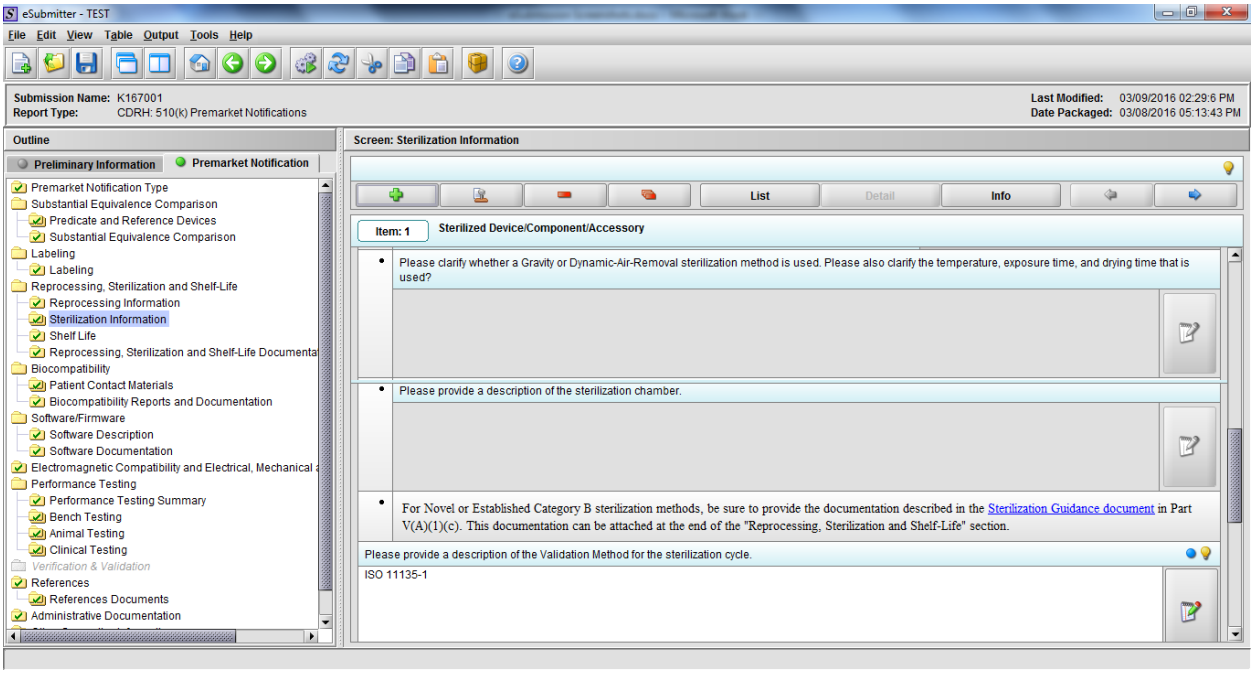
Sterilized Device/Component/Accessory
Step 2
Sterilizer
Is the sterilized part packaged as sterile?
Yes
For devices sterilized by the end user, please specifically cite the attachment and page number where the sterilization instructions are located for the end user.
For devices sterilized by the end user, please consult the Reprocessing Guidance for the documentation you should provide.
Step 3
Sterilization Method and Validation
Sterilization Method
Radiation (rare for End-User Sterilization) (Est A)
Dose (for radiation)
25 kGy
Sterilant residuals remaining on the device (for Ethylene Oxide)
Please clarify whether a Gravity or Dynamic-Air-Removal sterilization method is used. Please also clarify the temperature, exposure time, and drying time that is used?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Screen: Sterilization Information
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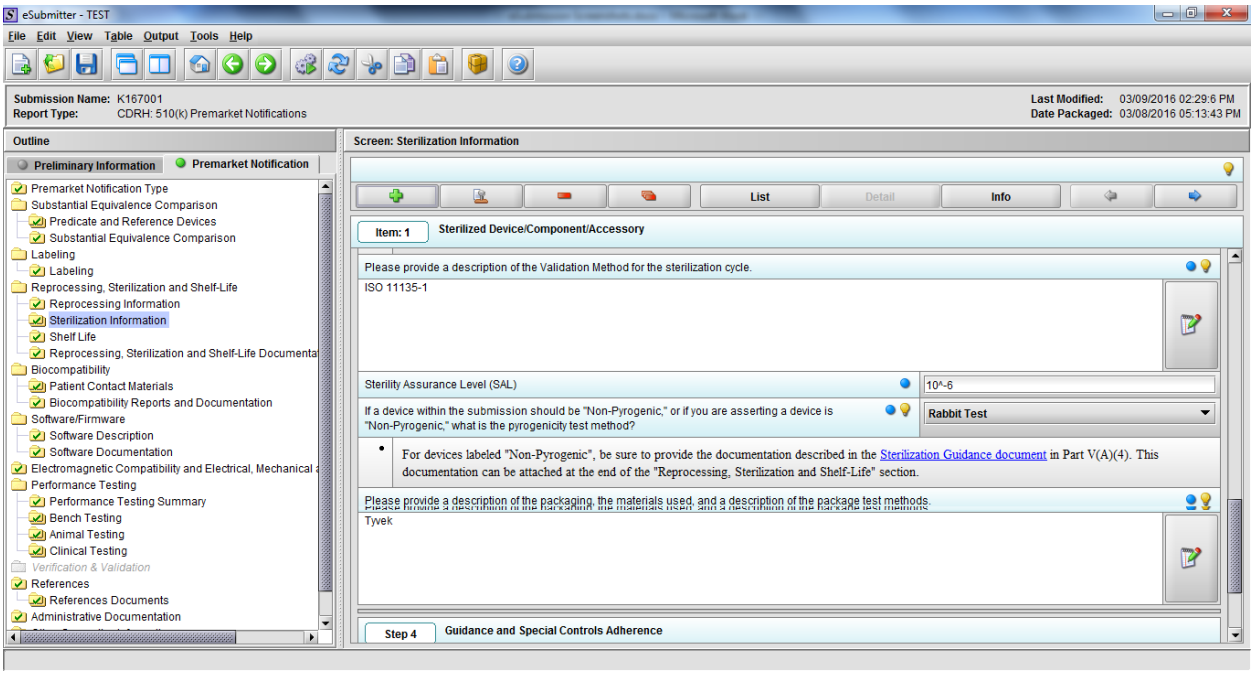
Detail
Info
Item: 1
Sterilized Device/Component/Accessory
Please clarify whether a Gravity or Dynamic-Air-Removal sterilization method is used. Please also clarify the temperature, exposure time, and drying time that is used?
Please provide a description of the sterilization chamber.
For Novel or Established Category B sterilization methods, be sure to provide the documentation described in the Sterilization Guidance document in Part V(A)(1)(c). This documentation can be attached at the end of the "Reprocessing, Sterilization and Shelf-Life" section.
Please provide a description of the Validation Method for the sterilization cycle.
ISO 11135-1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Submission Name: K167001
Report Type: CDRH: 510(k) Premarket Notifications
Last Modified: 03/09/2016 02:29:6 PM
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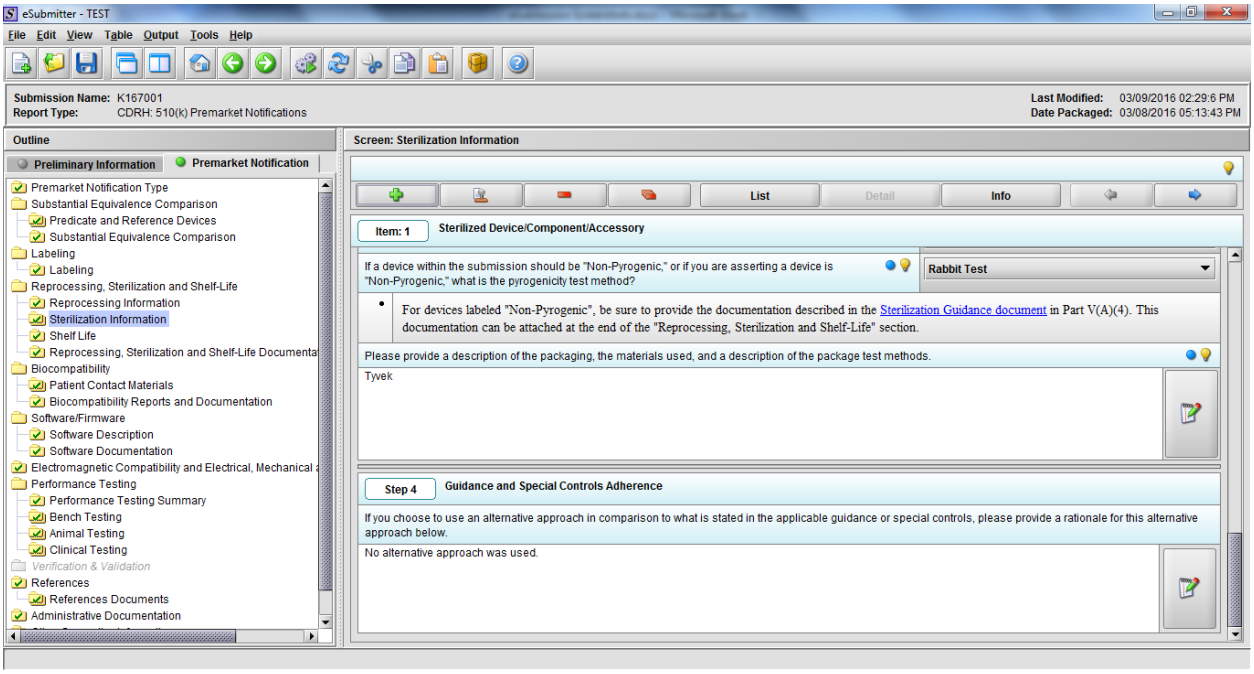
Item: 1
Sterilized Device/Component/Accessory
Please provide a description of the Validation Method for the sterilization cycle.
ISO 11135-1
Sterility Assurance Level (SAL)
10^-6
If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?
Rabbit Test
For devices labeled "Non-Pyrogenic", be sure to provide the documentation described in the Sterilization Guidance document in Part V(A)(4). This documentation can be attached at the end of the "Reprocessing, Sterilization and Shelf-Life" section.
Please provide a description of the packaging, the materials used, and a description of the package test methods.
Tyvek
Step 4
Guidance and Special Controls Adherence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Rabbit Test
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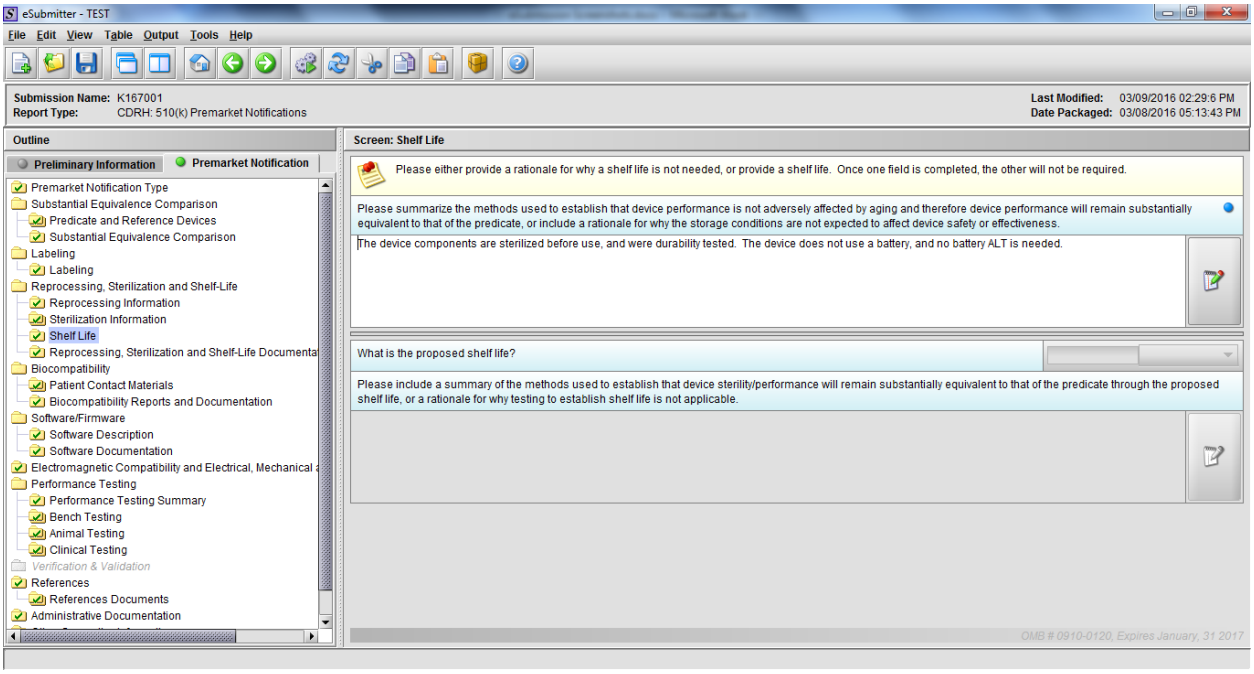
Please provide a description of the packaging, the materials used, and a description of the package test methods.
Tyvek
Step 4
Guidance and Special Controls Adherence
If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.
No alternative approach was used.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Please either provide a rationale for why a shelf life is not needed, or provide a shelf life. Once one field is completed, the other will not be required.
Please summarize the methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or include a rationale for why the storage conditions are not expected to affect device safety or effectiveness.
The device components are sterilized before use, and were durability tested. The device does not use a battery, and no battery ALT is needed.
What is the proposed shelf life?
Please include a summary of the methods used to establish that device sterility/performance will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.
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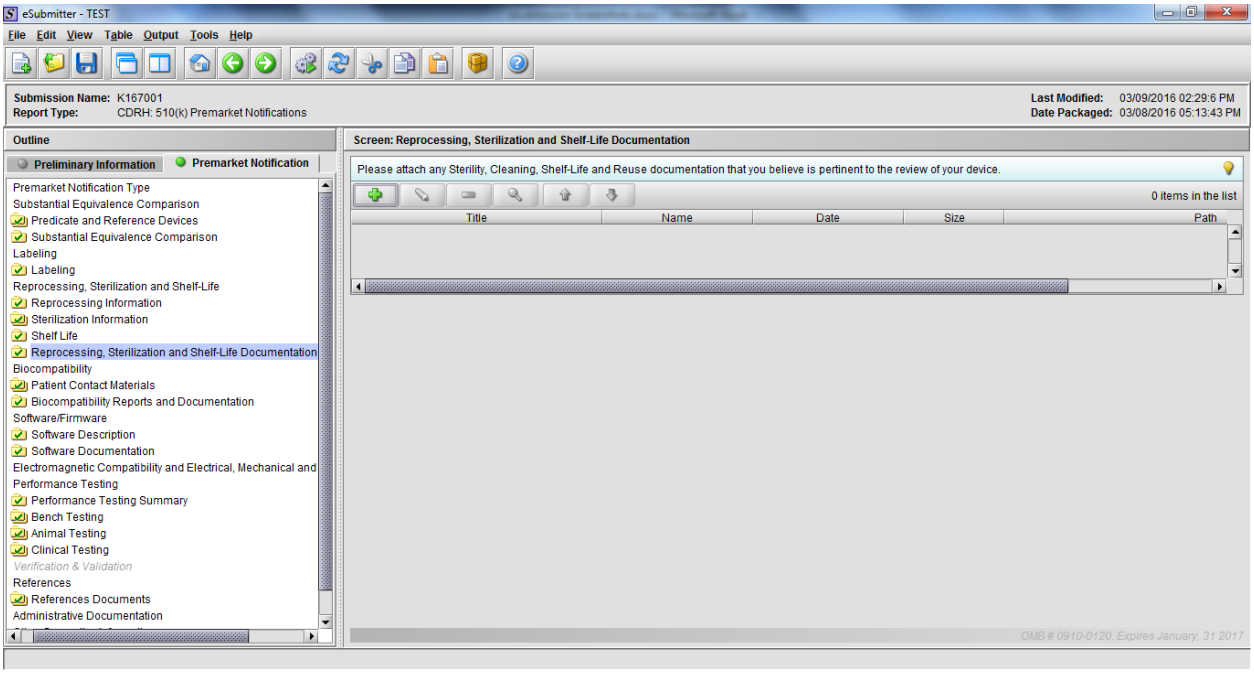
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Screen: Reprocessing, Sterilization and Shelf-Life Documentation
Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device.
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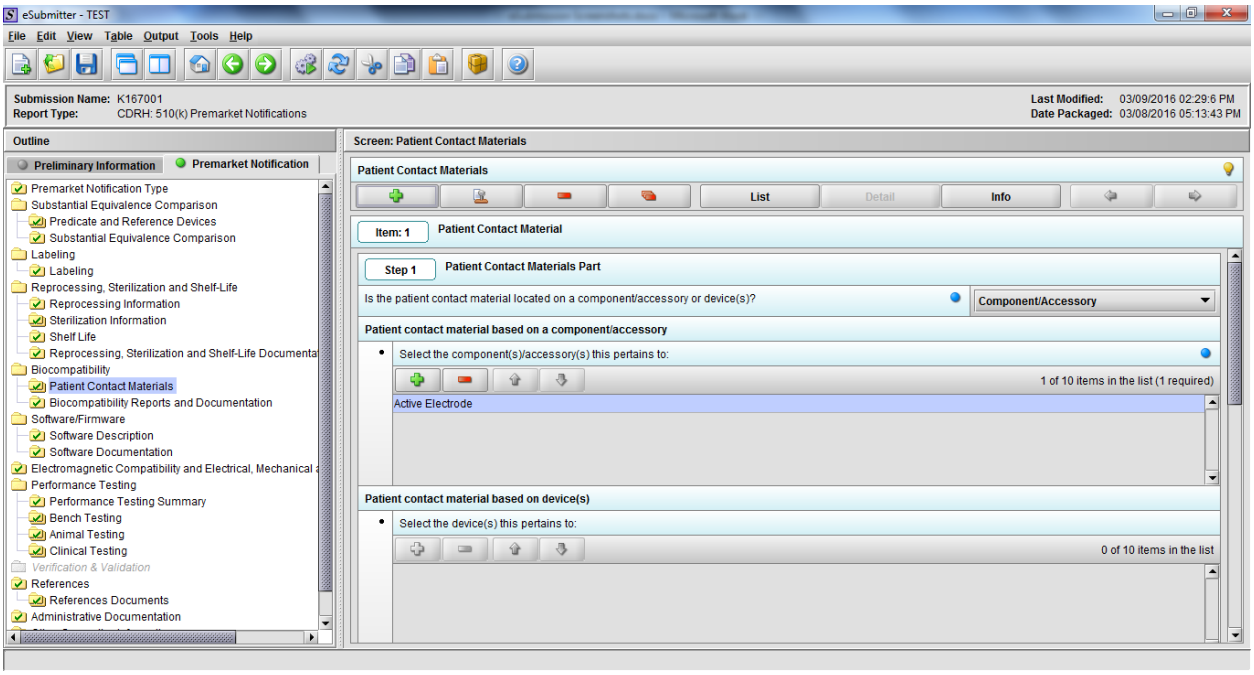
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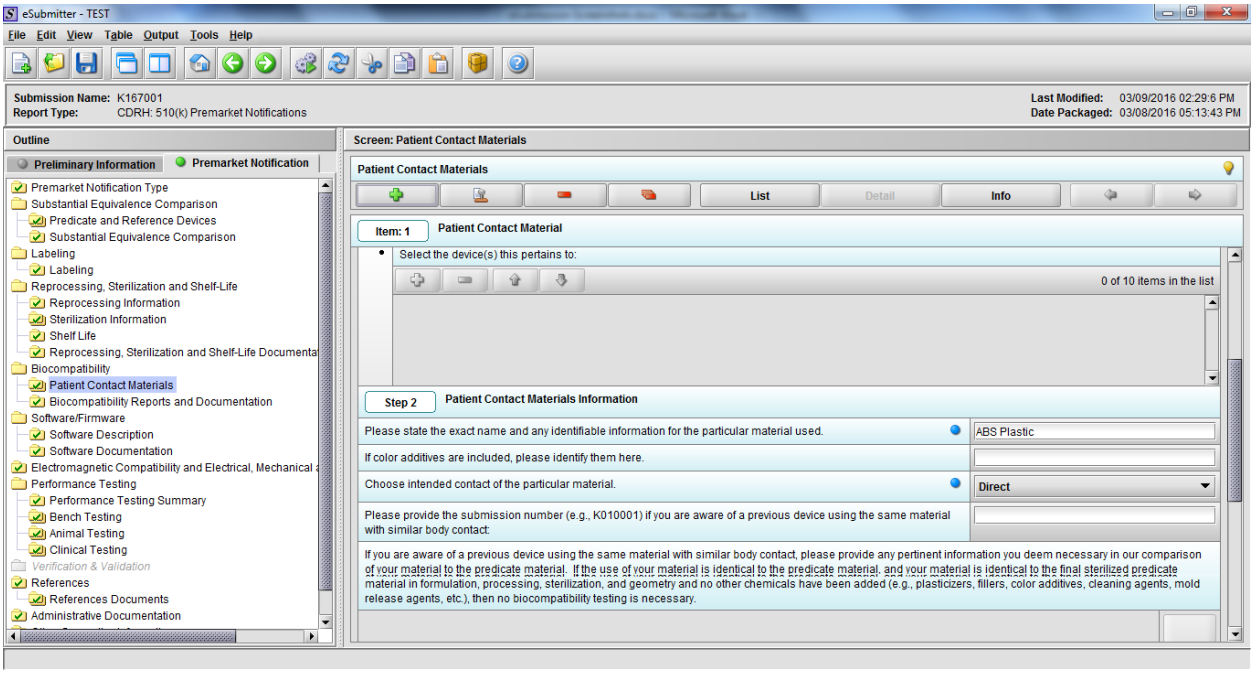
Patient Contact Material
Step 1
Patient Contact Materials Part
Is the patient contact material located on a component/accessory or device(s)?
Component/Accessory
Patient contact material based on a component/accessory
Select the component(s)/accessory(s) this pertains to:
1 of 10 items in the list (1 required)
Active Electrode
Patient contact material based on device(s)
Select the device(s) this pertains to:
0 of 10 items in the list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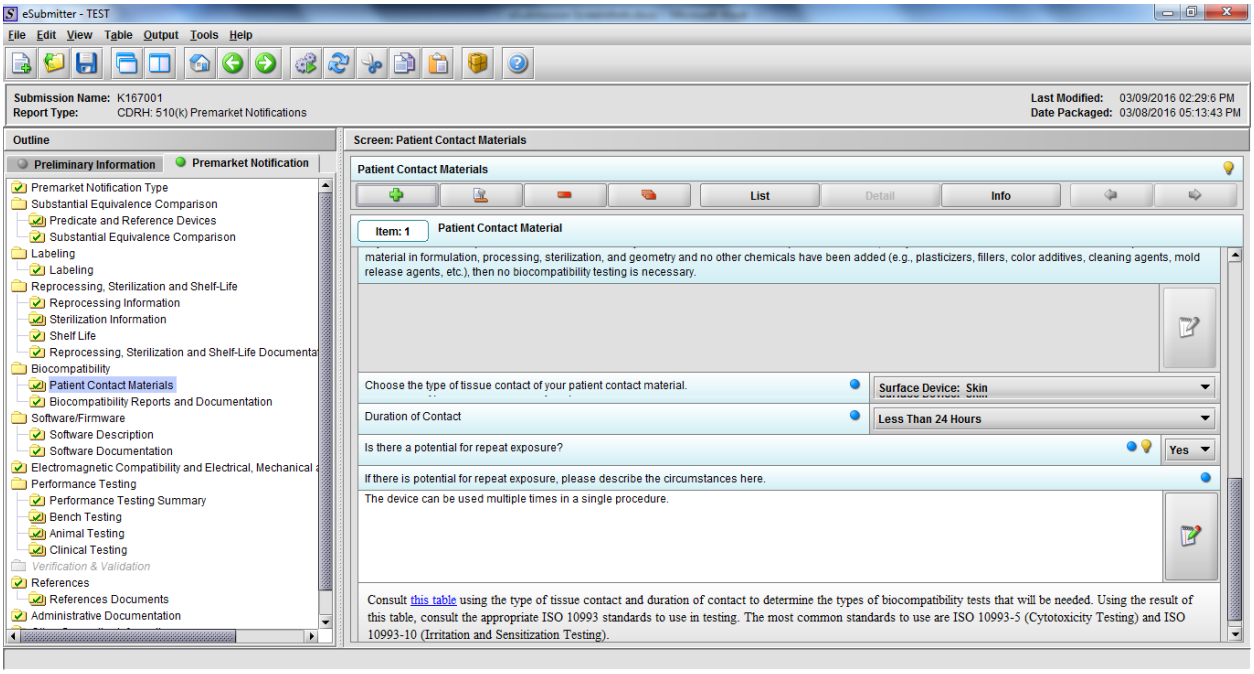
Patient Contact Material
Select the device(s) this pertains to:
0 of 10 items in the list
Step 2
Patient Contact Materials Information
Please state the exact name and any identifiable information for the particular material used.
ABS Plastic
If color additives are included, please identify them here.
Choose intended contact of the particular material.
Direct
Please provide the submission number (e.g., K010001) if you are aware of a previous device using the same material with similar body contact:
If you are aware of a previous device using the same material with similar body contact, please provide any pertinent information you deem necessary in our comparison of your material to the predicate material. If the use of your material is identical to the predicate material, and your material is identical to the final sterilized predicate material in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.), then no biocompatibility testing is necessary.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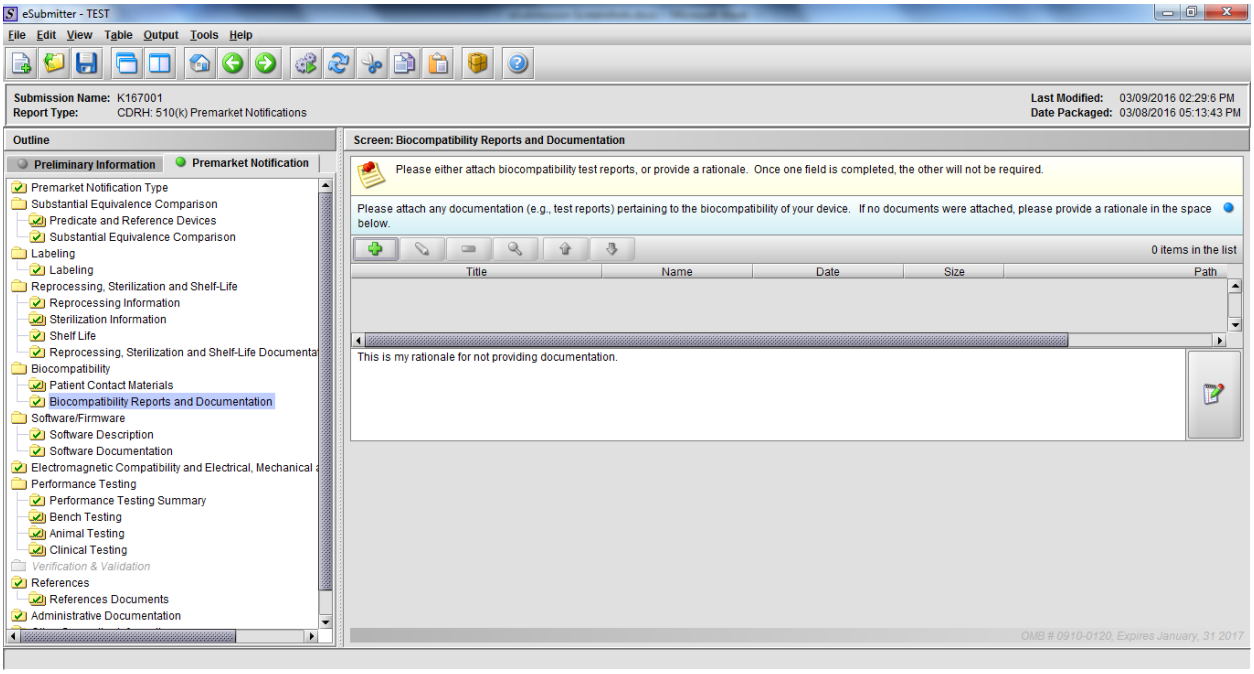
Patient Contact Material
material in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.), then no biocompatibility testing is necessary.
Choose the type of tissue contact of your patient contact material.
Surface Device: Skin
Duration of Contact
Less Than 24 Hours
Is there a potential for repeat exposure?
Yes
If there is potential for repeat exposure, please describe the circumstances here.
The device can be used multiple times in a single procedure.
Consult this table using the type of tissue contact and duration of contact to determine the types of biocompatibility tests that will be needed. Using the result of this table, consult the appropriate ISO 10993 standards to use in testing. The most common standards to use are ISO 10993-5 (Cytotoxicity Testing) and ISO 10993-10 (Irritation and Sensitization Testing).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Screen: Biocompatibility Reports and Documentation
Please either attach biocompatibility test reports, or provide a rationale. Once one field is completed, the other will not be required.
Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no documents were attached, please provide a rationale in the space below.
0 items in the list
Title
Name
Date
Size
Path
This is my rationale for not providing documentation.
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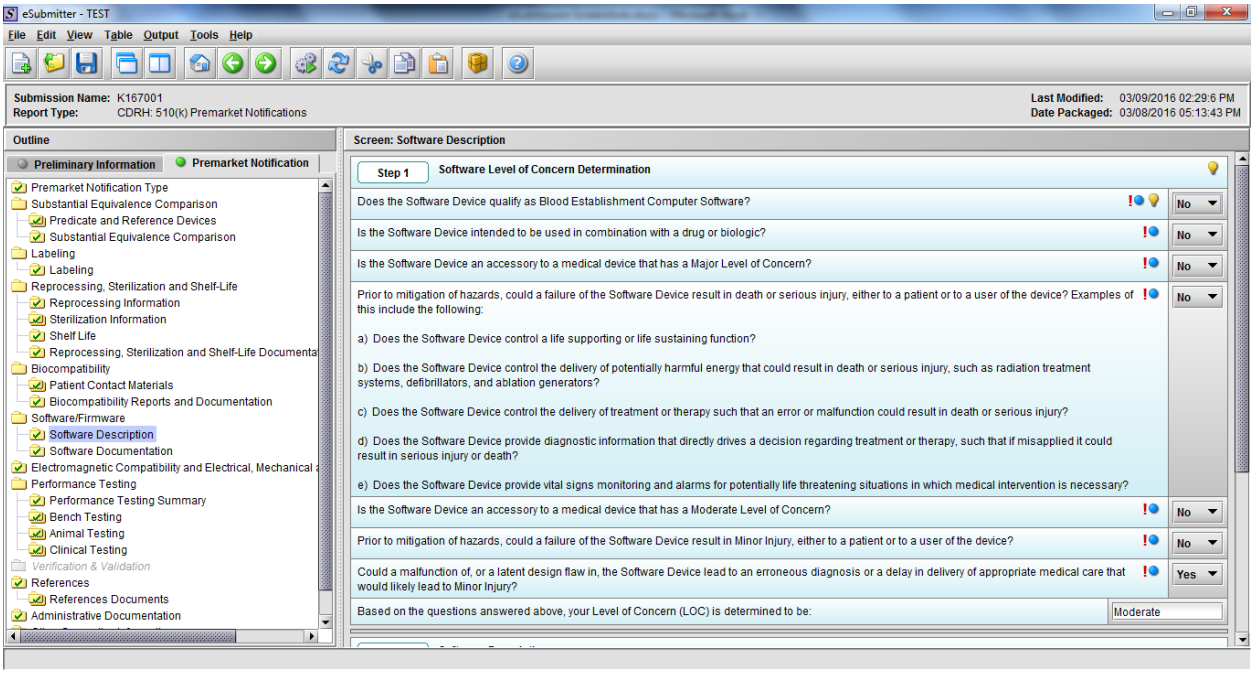
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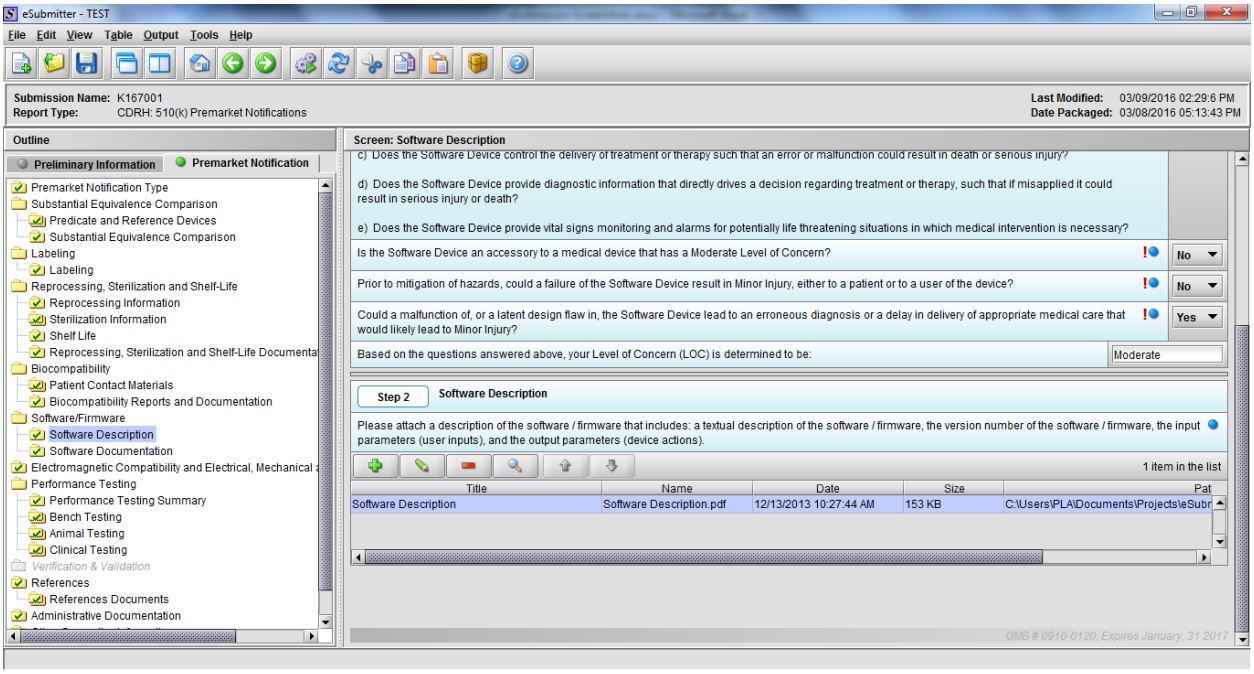
Step 1
Software Level of Concern Determination
Does the Software Device qualify as Blood Establishment Computer Software? No
Is the Software Device intended to be used in combination with a drug or biologic? No
Is the Software Device an accessory to a medical device that has a Major Level of Concern? No
Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
a) Does the Software Device control a life supporting or life sustaining function?
b) Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?
c) Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?
d) Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
e) Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?
No
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? No
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device? No
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury? Yes
Based on the questions answered above, your Level of Concern (LOC) is determined to be: Moderate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d) Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
e) Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?
No
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?
No
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?
Yes
Based on the questions answered above, your Level of Concern (LOC) is determined to be:
Moderate
Step 2
Software Description
Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).
1 item in the list
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Software Description
Software Description.pdf
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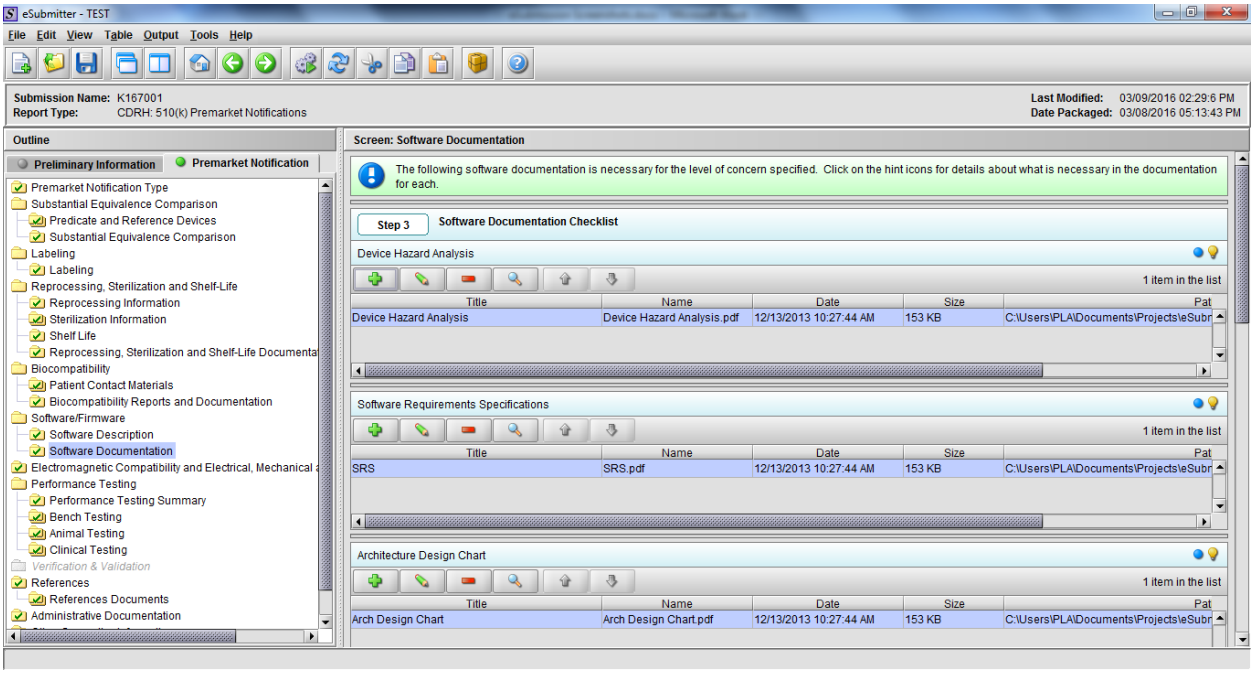
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Screen: Software Documentation
The following software documentation is necessary for the level of concern specified. Click on the hint icons for details about what is necessary in the documentation for each.
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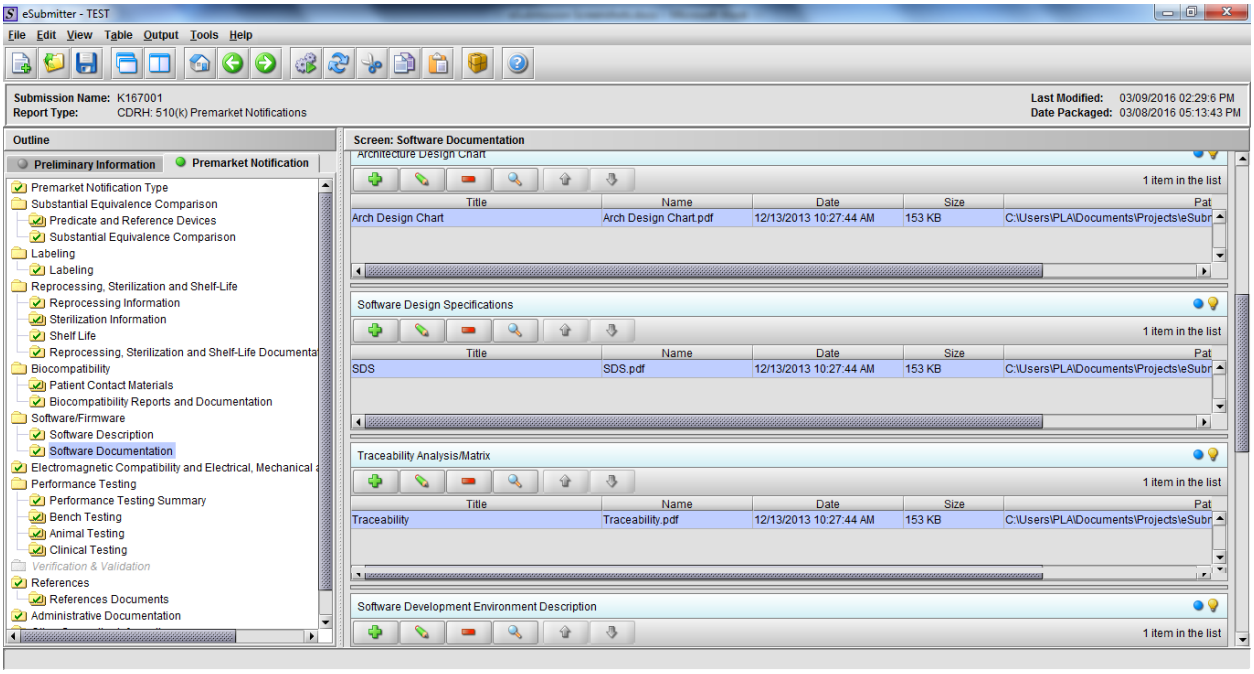
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Software Development Environment Description
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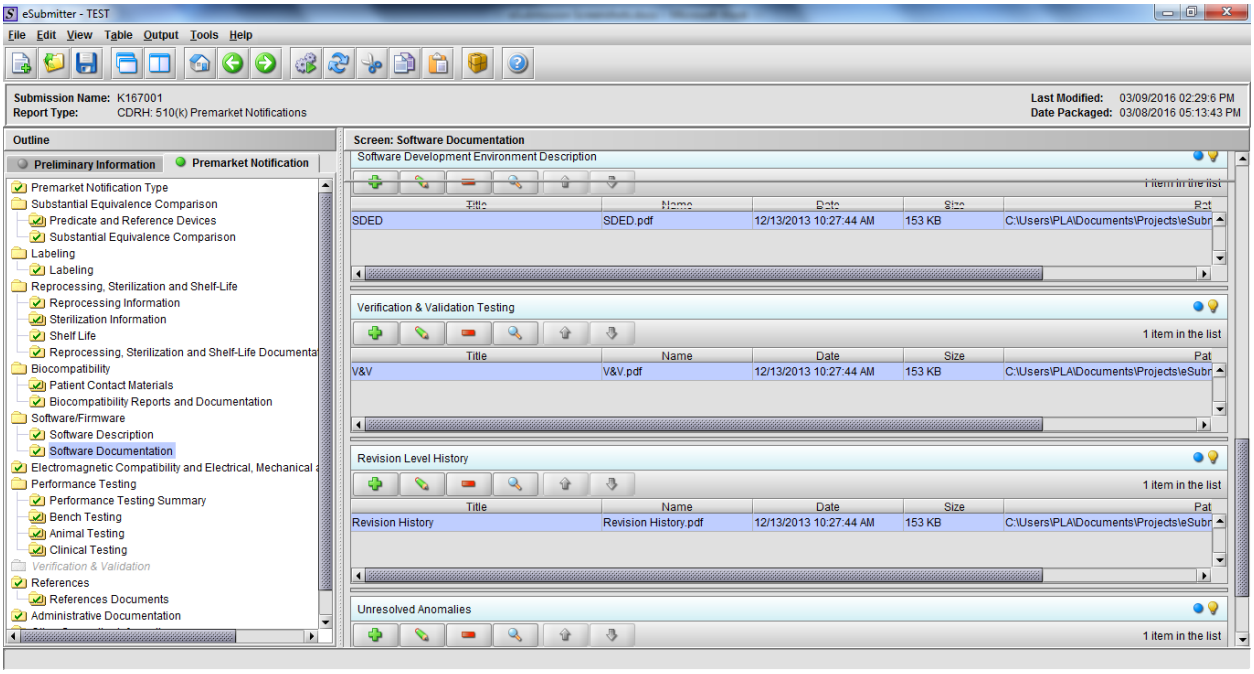
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Revision History Revision History.pdf 12/13/2013 10:27:44 AM 153 KB C:\Users\PLA\Documents\Projects\eSubr
Unresolved Anomalies
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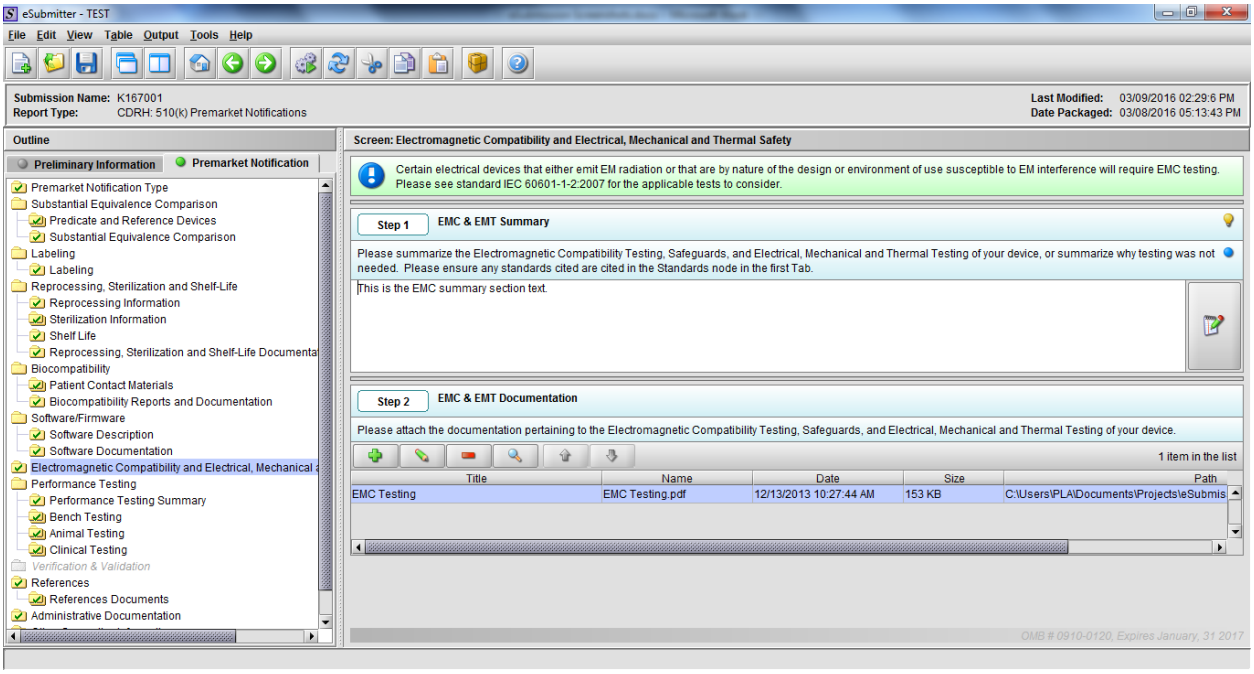
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Last Modified: 03/09/2016 02:29:6 PM
Date Packaged: 03/08/2016 05:13:43 PM
Outline
Preliminary Information
Premarket Notification
Premarket Notification Type
Substantial Equivalence Comparison
Predicate and Reference Devices
Substantial Equivalence Comparison
Labeling
Labeling
Reprocessing, Sterilization and Shelf-Life
Reprocessing Information
Sterilization Information
Shelf Life
Reprocessing, Sterilization and Shelf-Life Documenta
Biocompatibility
Patient Contact Materials
Biocompatibility Reports and Documentation
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Electromagnetic Compatibility and Electrical, Mechanical
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Bench Testing
Animal Testing
Clinical Testing
Verification & Validation
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References Documents
Administrative Documentation
Screen: Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
Certain electrical devices that either emit EM radiation or that are by nature of the design or environment of use susceptible to EM interference will require EMC testing. Please see standard IEC 60601-1-2:2007 for the applicable tests to consider.
Step 1
EMC & EMT Summary
Please summarize the Electromagnetic Compatibility Testing, Safeguards, and Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited are cited in the Standards node in the first Tab.
This is the EMC summary section text.
Step 2
EMC & EMT Documentation
Please attach the documentation pertaining to the Electromagnetic Compatibility Testing, Safeguards, and Electrical, Mechanical and Thermal Testing of your device.
1 item in the list
Title
Name
Date
Size
Path
EMC Testing
EMC Testing.pdf
12/13/2013 10:27:44 AM
153 KB
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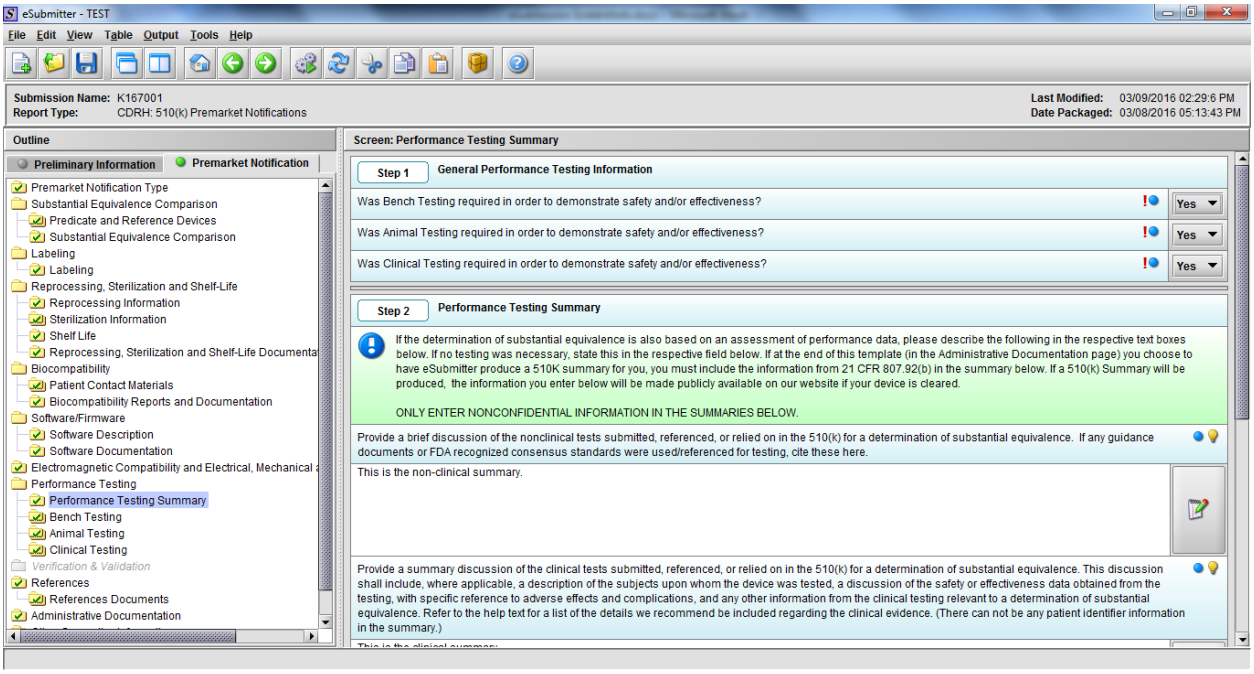
OMB # 0910-0120, Expires January, 31 2017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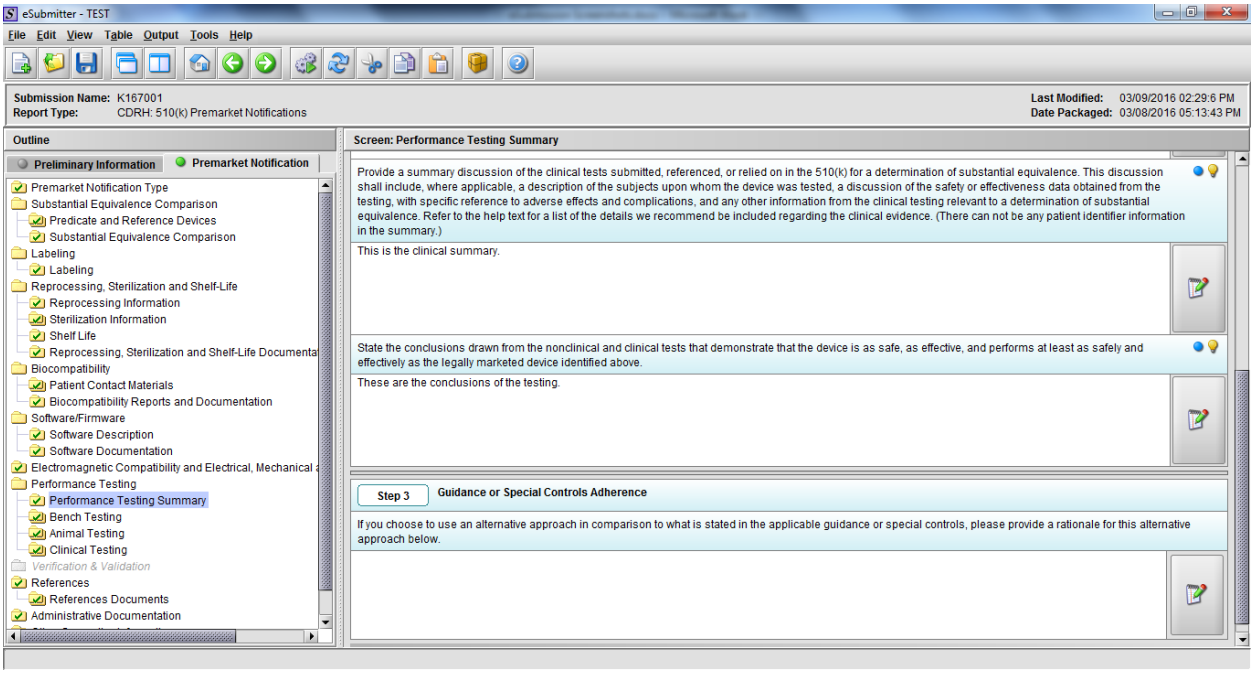
Administrative Documentation
Screen: Performance Testing Summary
Step 1
General Performance Testing Information
Was Bench Testing required in order to demonstrate safety and/or effectiveness?
Yes
Was Animal Testing required in order to demonstrate safety and/or effectiveness?
Yes
Was Clinical Testing required in order to demonstrate safety and/or effectiveness?
Yes
Step 2
Performance Testing Summary
If the determination of substantial equivalence is also based on an assessment of performance data, please describe the following in the respective text boxes below. If no testing was necessary, state this in the respective field below. If at the end of this template (in the Administrative Documentation page) you choose to have eSubmitter produce a 510K summary for you, you must include the information from 21 CFR 807.92(b) in the summary below. If a 510(k) Summary will be produced, the information you enter below will be made publicly available on our website if your device is cleared.
ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARIES BELOW.
Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.
This is the non-clinical summary.
Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the clinical evidence. (There can not be any patient identifier information in the summary.)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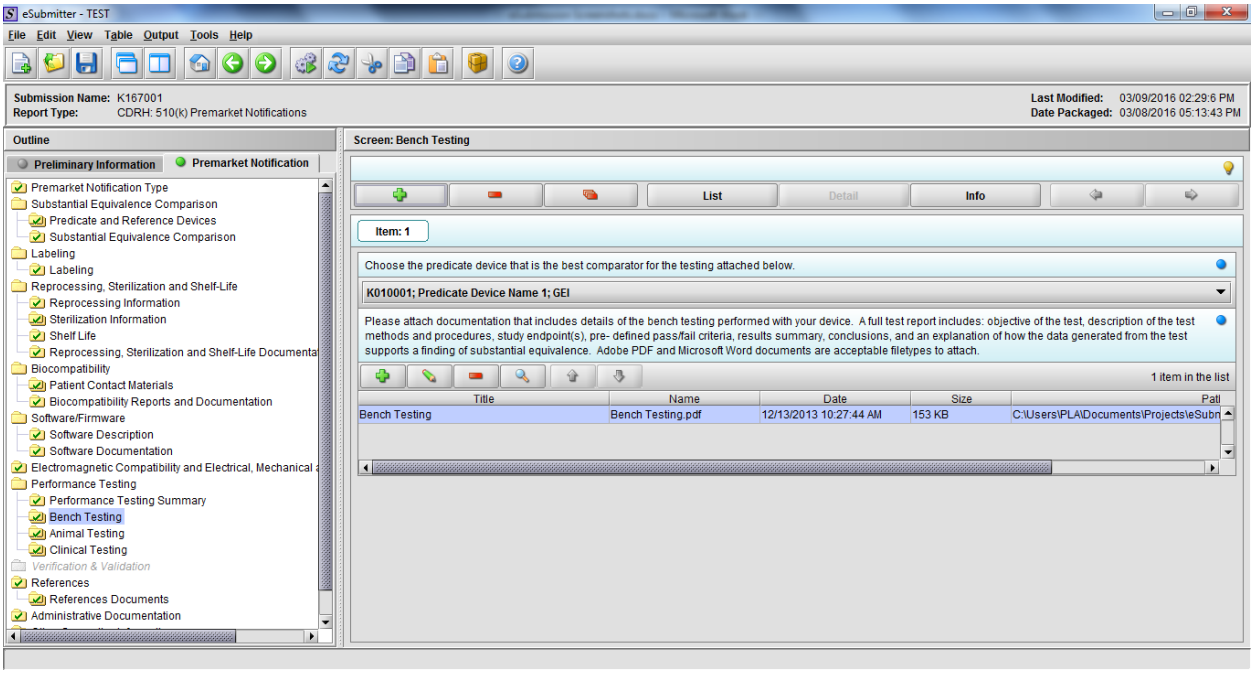
Screen: Performance Testing Summary
Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the clinical evidence. (There can not be any patient identifier information in the summary.)
This is the clinical summary.
State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified above.
These are the conclusions of the testing.
Step 3
Guidance or Special Controls Adherence
If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.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Screen: Bench Testing
List
Detail
Info
Item: 1
Choose the predicate device that is the best comparator for the testing attached below.
K010001; Predicate Device Name 1; GEI
Please attach documentation that includes details of the bench testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. Adobe PDF and Microsoft Word documents are acceptable filetypes to attach.
1 item in the list
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Size
Path
Bench Testing
Bench Testing.pdf
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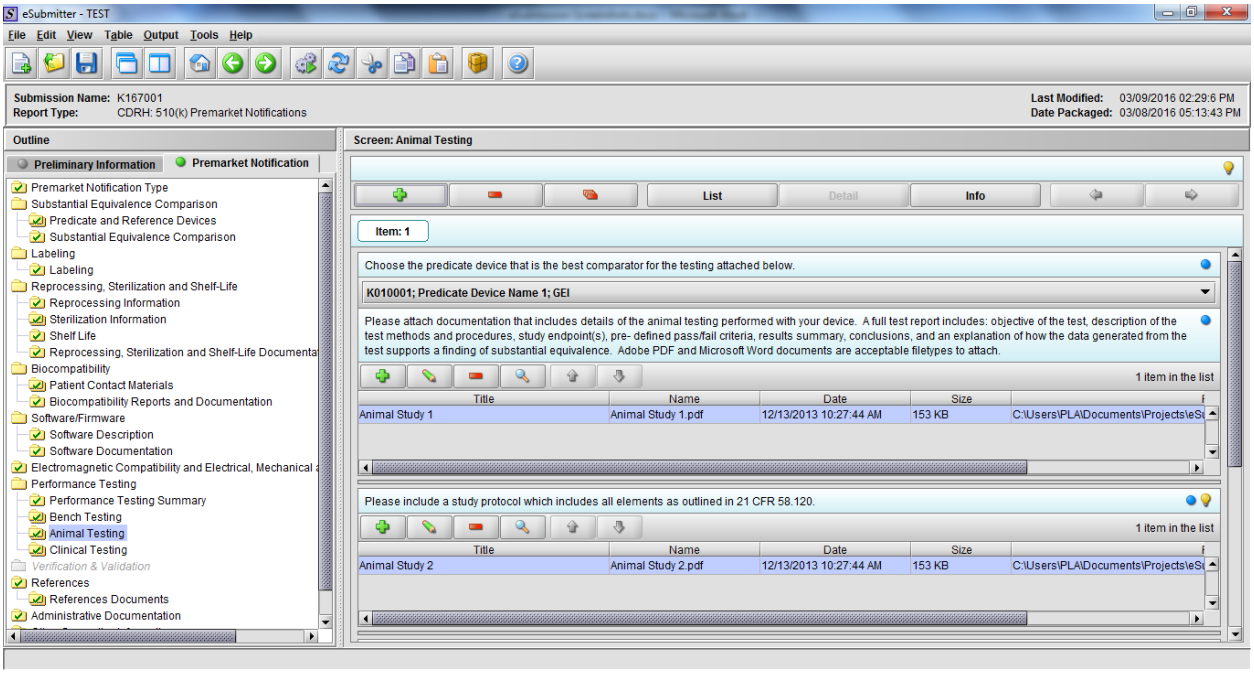
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List
Detail
Info
Item: 1
Choose the predicate device that is the best comparator for the testing attached below.
K010001; Predicate Device Name 1; GEI
Please attach documentation that includes details of the animal testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. Adobe PDF and Microsoft Word documents are acceptable filetypes to attach.
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Animal Study 1
Animal Study 1.pdf
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Please include a study protocol which includes all elements as outlined in 21 CFR 58.120.
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Animal Study 2
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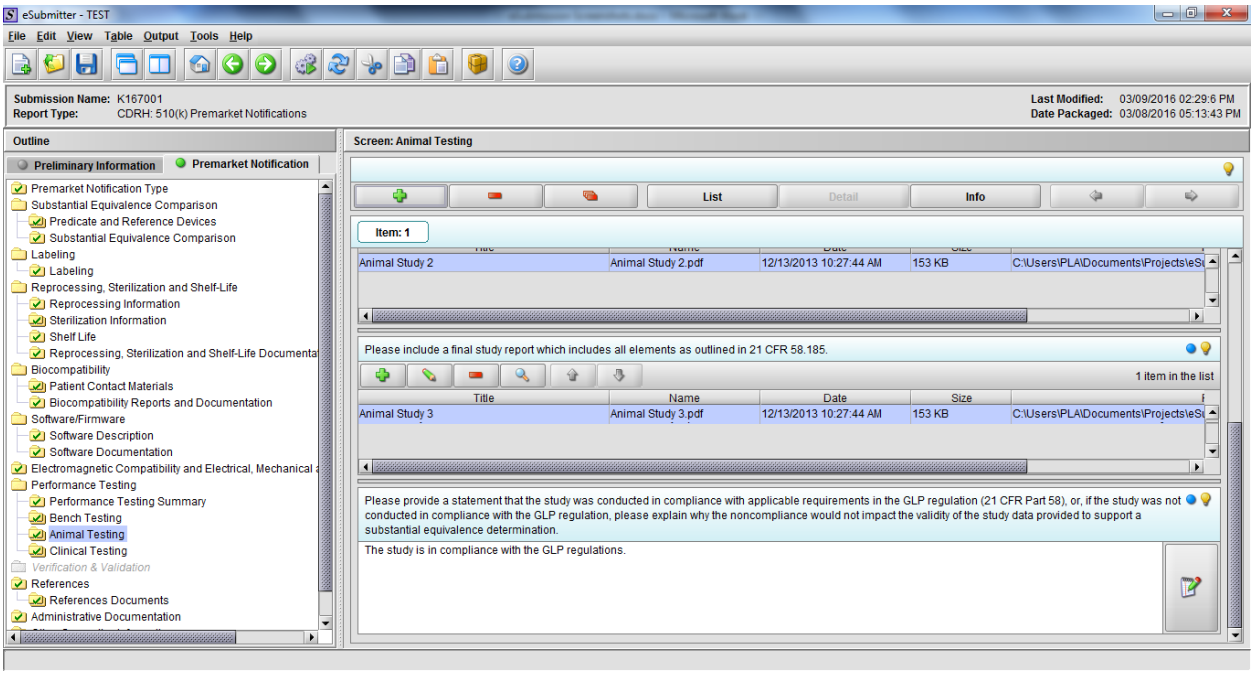
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Item: 1
Animal Study 2
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Please include a final study report which includes all elements as outlined in 21 CFR 58.185.
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Animal Study 3
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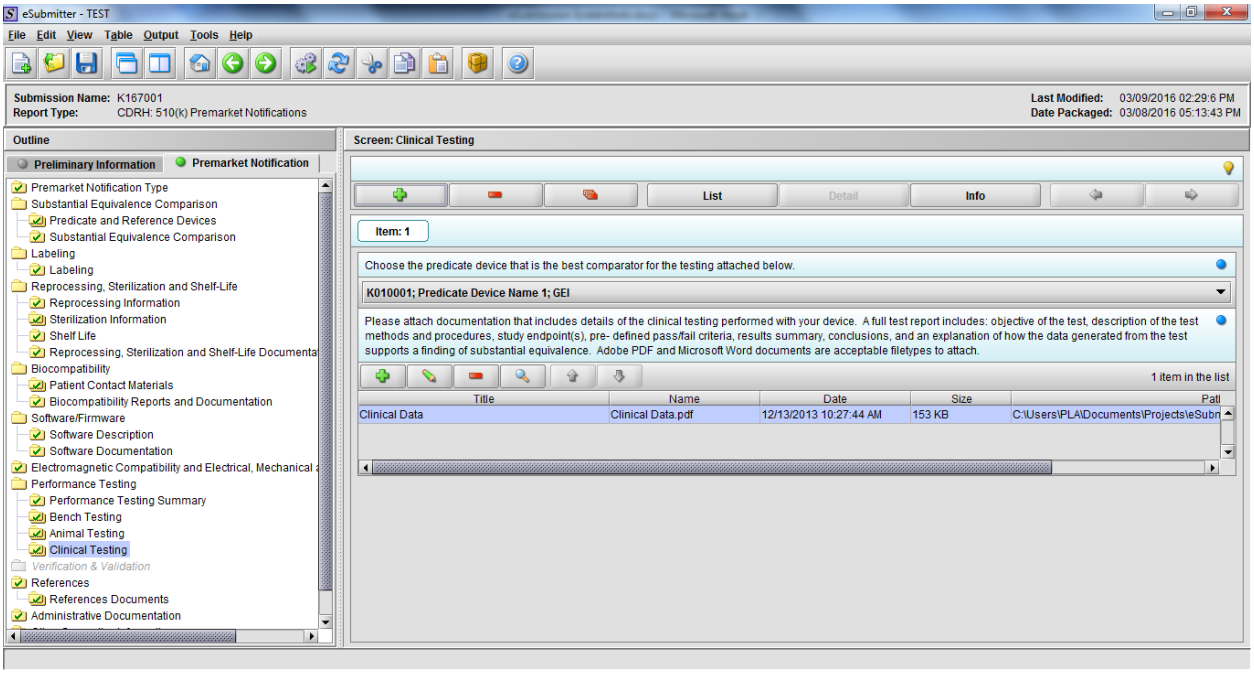
Please provide a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, please explain why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.
The study is in compliance with the GLP regulations.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Screen: Clinical Testing
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Item: 1
Choose the predicate device that is the best comparator for the testing attached below.
K010001; Predicate Device Name 1; GEI
Please attach documentation that includes details of the clinical testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. Adobe PDF and Microsoft Word documents are acceptable filetypes to attach.
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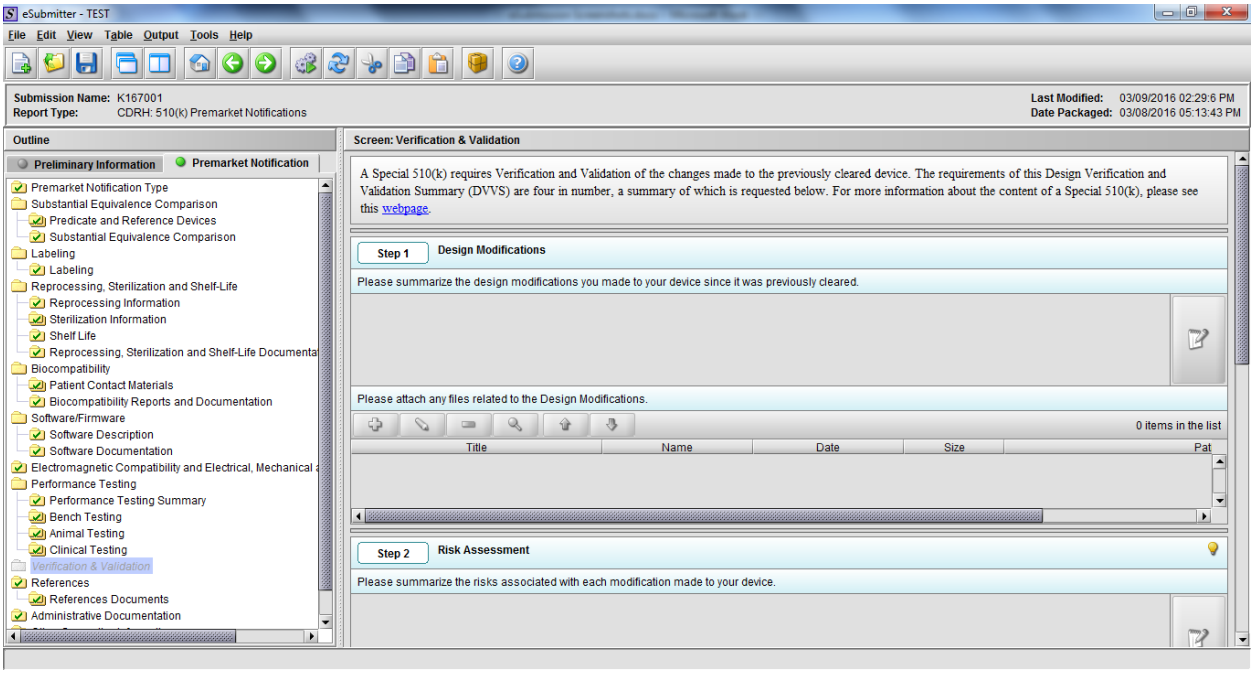
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Screen: Verification & Validation
A Special 510(k) requires Verification and Validation of the changes made to the previously cleared device. The requirements of this Design Verification and Validation Summary (DVVS) are four in number, a summary of which is requested below. For more information about the content of a Special 510(k), please see this webpage.
Step 1
Design Modifications
Please summarize the design modifications you made to your device since it was previously cleared.
Please attach any files related to the Design Modifications.
0 items in the list
Title
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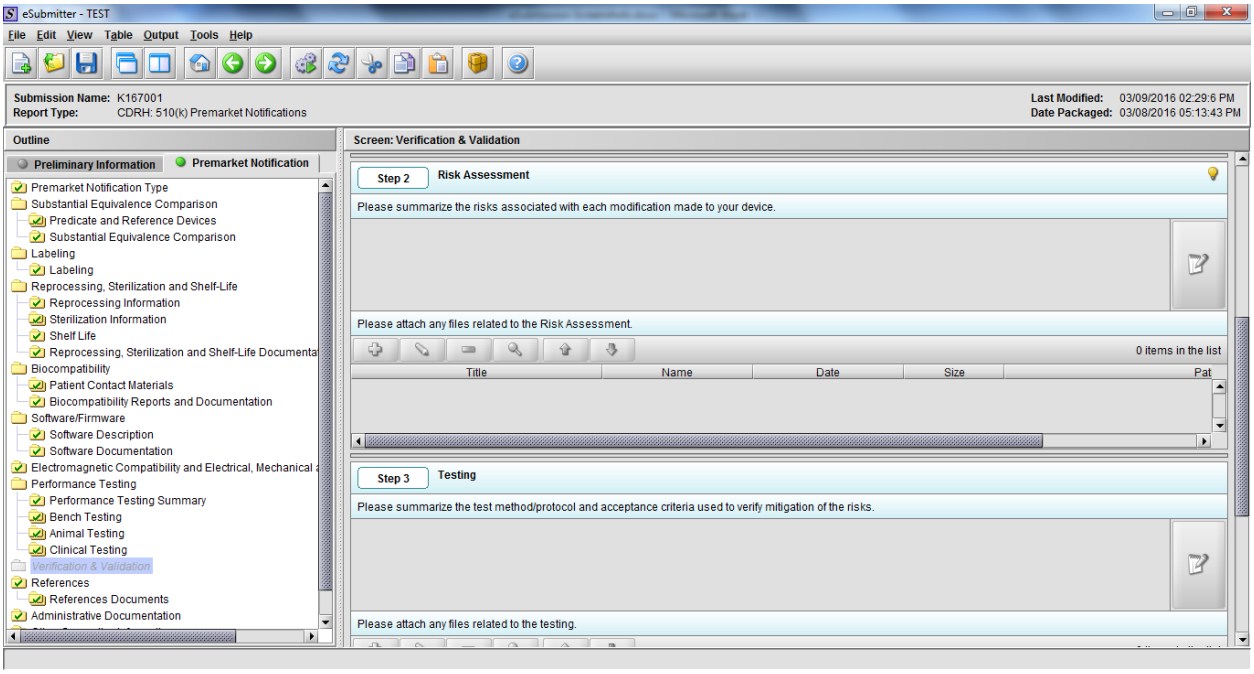
Step 2
Risk Assessment
Please summarize the risks associated with each modification made to your device.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Screen: Verification & Validation
Step 2
Risk Assessment
Please summarize the risks associated with each modification made to your device.
Please attach any files related to the Risk Assessment.
0 items in the list
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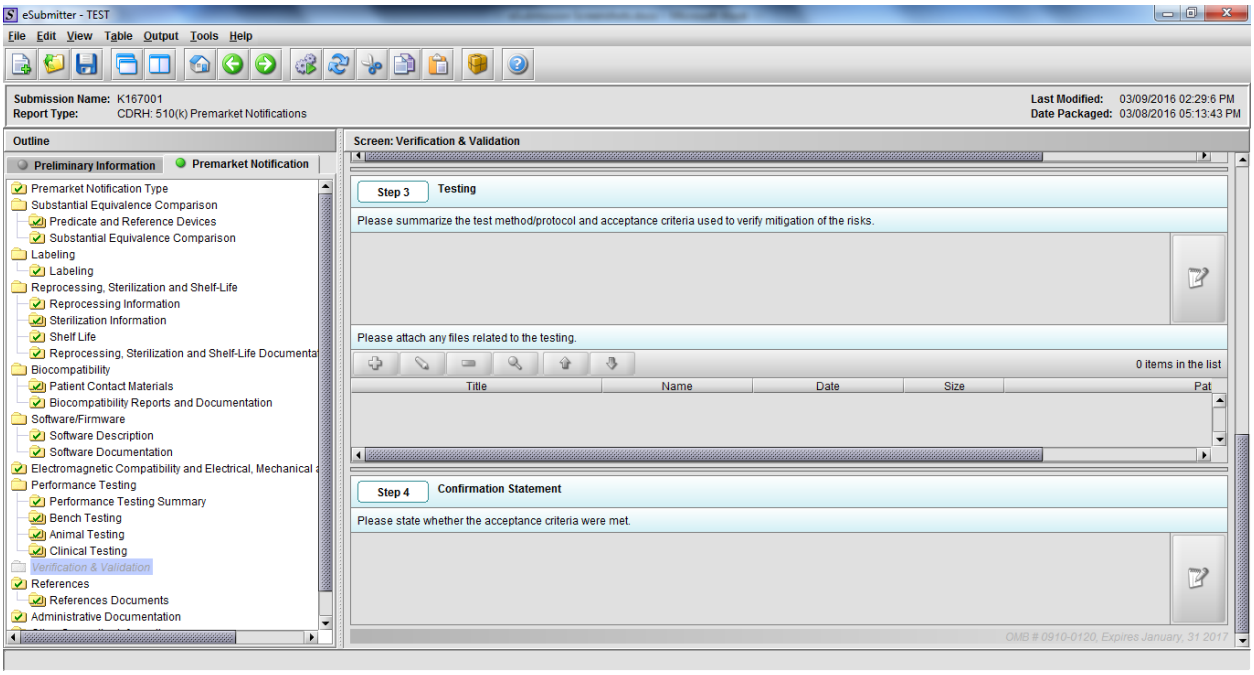
Step 3
Testing
Please summarize the test method/protocol and acceptance criteria used to verify mitigation of the risks.
Please attach any files related to the testing.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Step 3
Testing
Please summarize the test method/protocol and acceptance criteria used to verify mitigation of the risks.
Please attach any files related to the testing.
0 items in the list
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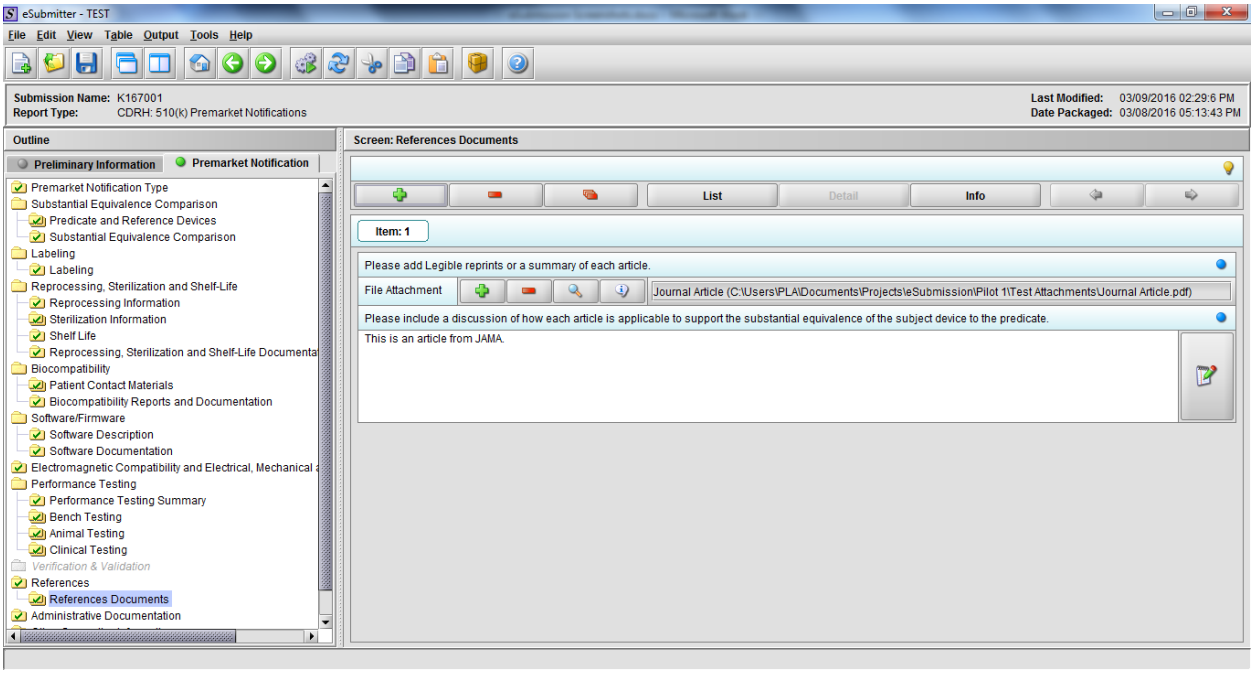
Step 4
Confirmation Statement
Please state whether the acceptance criteria were met.
OMB # 0910-0120, Expires January, 31 2017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Screen: References Documents
List
Detail
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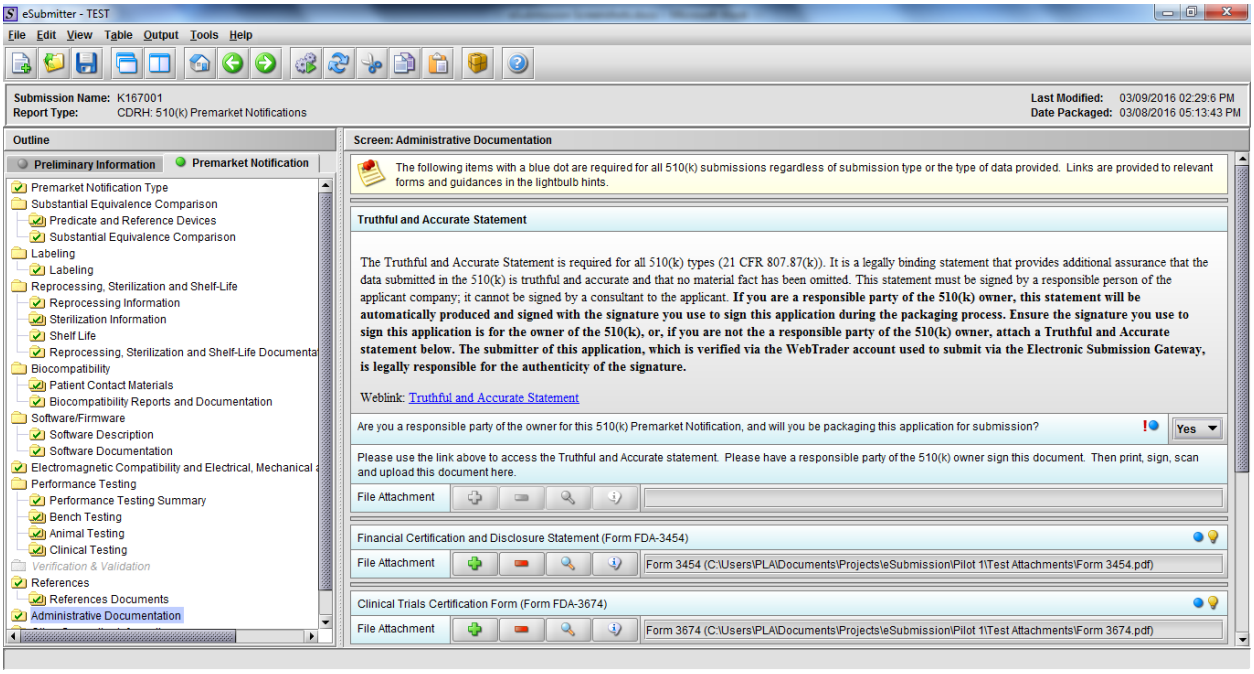
Item: 1
Please add Legible reprints or a summary of each article.
File Attachment
Journal Article (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Journal Article.pdf)
Please include a discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.
This is an article from JAMA.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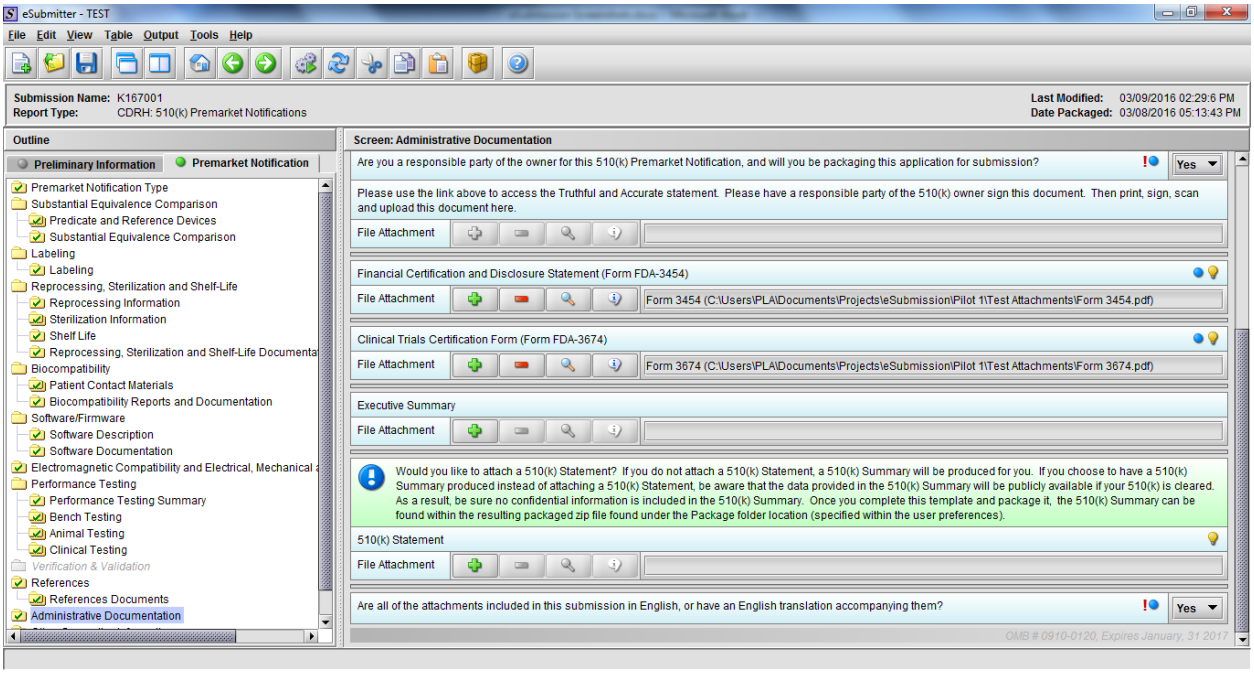
The following items with a blue dot are required for all 510(k) submissions regardless of submission type or the type of data provided. Links are provided to relevant forms and guidances in the lightbulb hints.
Truthful and Accurate Statement
The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with the signature you use to sign this application during the packaging process. Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not the a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below. The submitter of this application, which is verified via the WebTrader account used to submit via the Electronic Submission Gateway, is legally responsible for the authenticity of the signature.
Weblink: Truthful and Accurate Statement
Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be packaging this application for submission?
Yes
Please use the link above to access the Truthful and Accurate statement. Please have a responsible party of the 510(k) owner sign this document. Then print, sign, scan and upload this document here.
File Attachment
Financial Certification and Disclosure Statement (Form FDA-3454)
File Attachment
Form 3454 (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Form 3454.pdf)
Clinical Trials Certification Form (Form FDA-3674)
File Attachment
Form 3674 (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Form 3674.pdf)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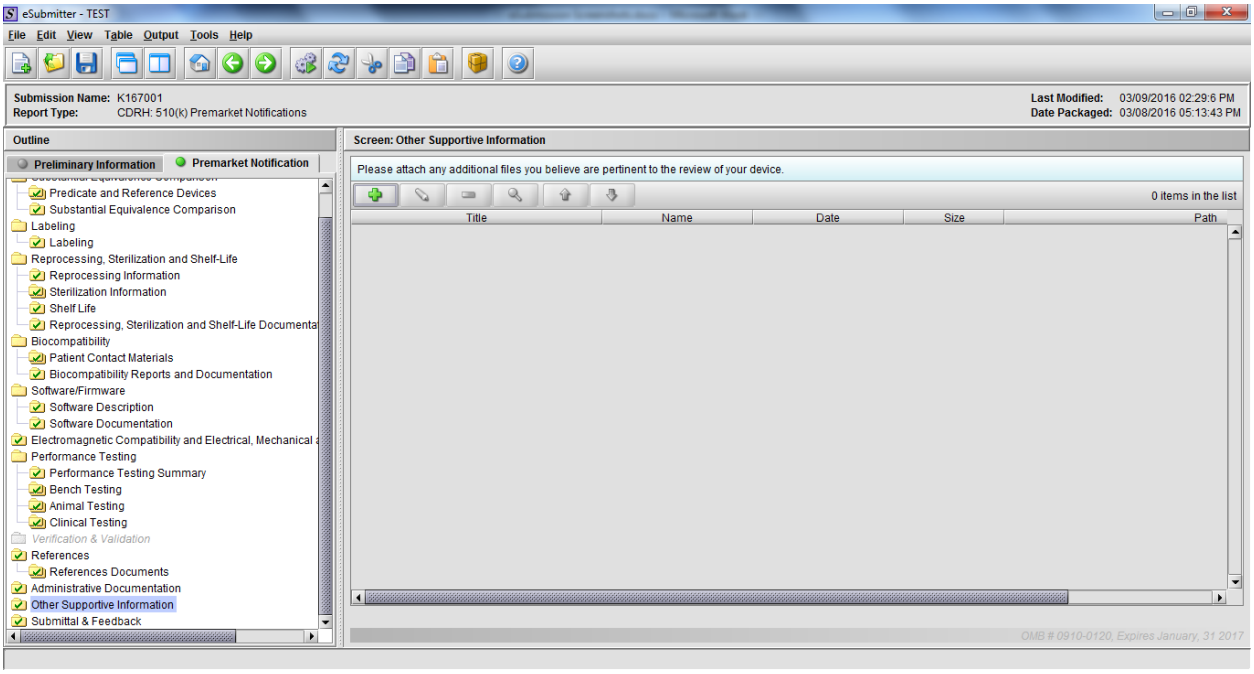
Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be packaging this application for submission?
Yes
Please use the link above to access the Truthful and Accurate statement. Please have a responsible party of the 510(k) owner sign this document. Then print, sign, scan and upload this document here.
File Attachment
Financial Certification and Disclosure Statement (Form FDA-3454)
File Attachment
Form 3454 (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Form 3454.pdf)
Clinical Trials Certification Form (Form FDA-3674)
File Attachment
Form 3674 (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\Form 3674.pdf)
Executive Summary
File Attachment
Would you like to attach a 510(k) Statement? If you do not attach a 510(k) Statement, a 510(k) Summary will be produced for you. If you choose to have a 510(k) Summary produced instead of attaching a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. Once you complete this template and package it, the 510(k) Summary can be found within the resulting packaged zip file found under the Package folder location (specified within the user preferences).
510(k) Statement
File Attachment
Are all of the attachments included in this submission in English, or have an English translation accompanying them?
Yes
OMB # 0910-0120, Expires January, 31 2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: K167001
Report Type: CDRH: 510(k) Premarket Notifications
Last Modified: 03/09/2016 02:29:6 PM
Date Packaged: 03/08/2016 05:13:43 PM
Outline
Preliminary Information
Premarket Notification
Predicate and Reference Devices
Substantial Equivalence Comparison
Labeling
Labeling
Reprocessing, Sterilization and Shelf-Life
Reprocessing Information
Sterilization Information
Shelf Life
Reprocessing, Sterilization and Shelf-Life Documenta
Biocompatibility
Patient Contact Materials
Biocompatibility Reports and Documentation
Software/Firmware
Software Description
Software Documentation
Electromagnetic Compatibility and Electrical, Mechanical
Performance Testing
Performance Testing Summary
Bench Testing
Animal Testing
Clinical Testing
Verification & Validation
References
References Documents
Administrative Documentation
Other Supportive Information
Submittal & Feedback
Screen: Other Supportive Information
Please attach any additional files you believe are pertinent to the review of your device.
0 items in the list
Title
Name
Date
Size
Path
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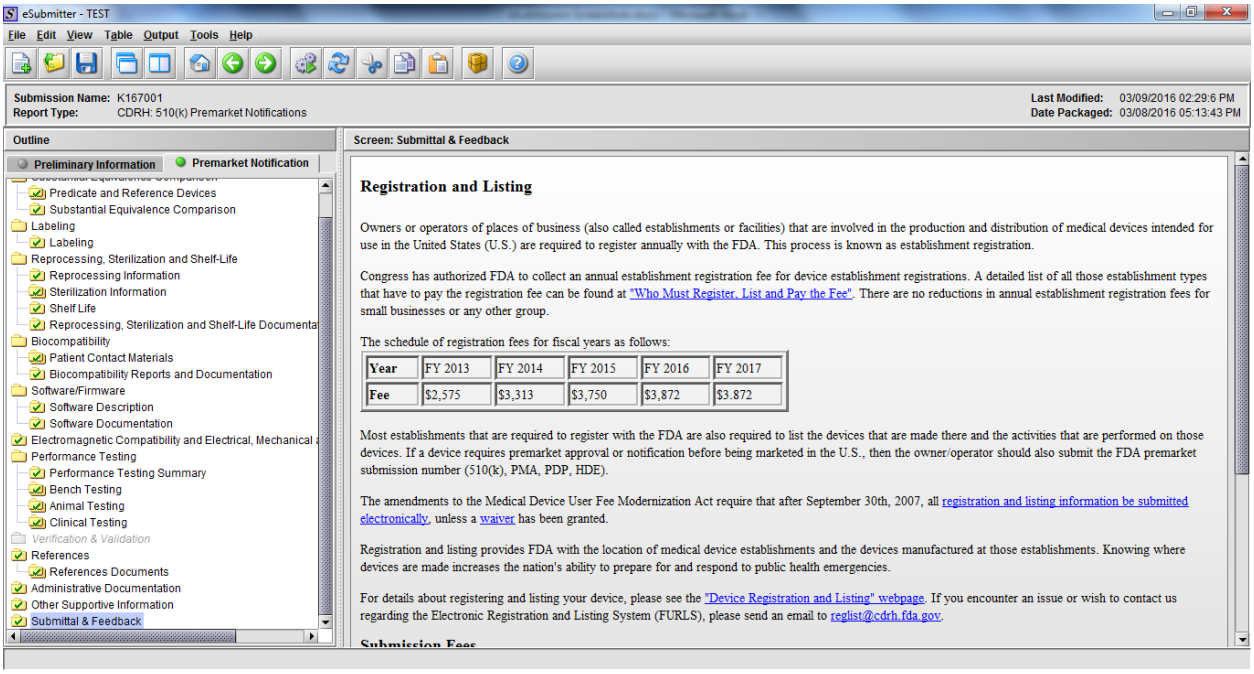
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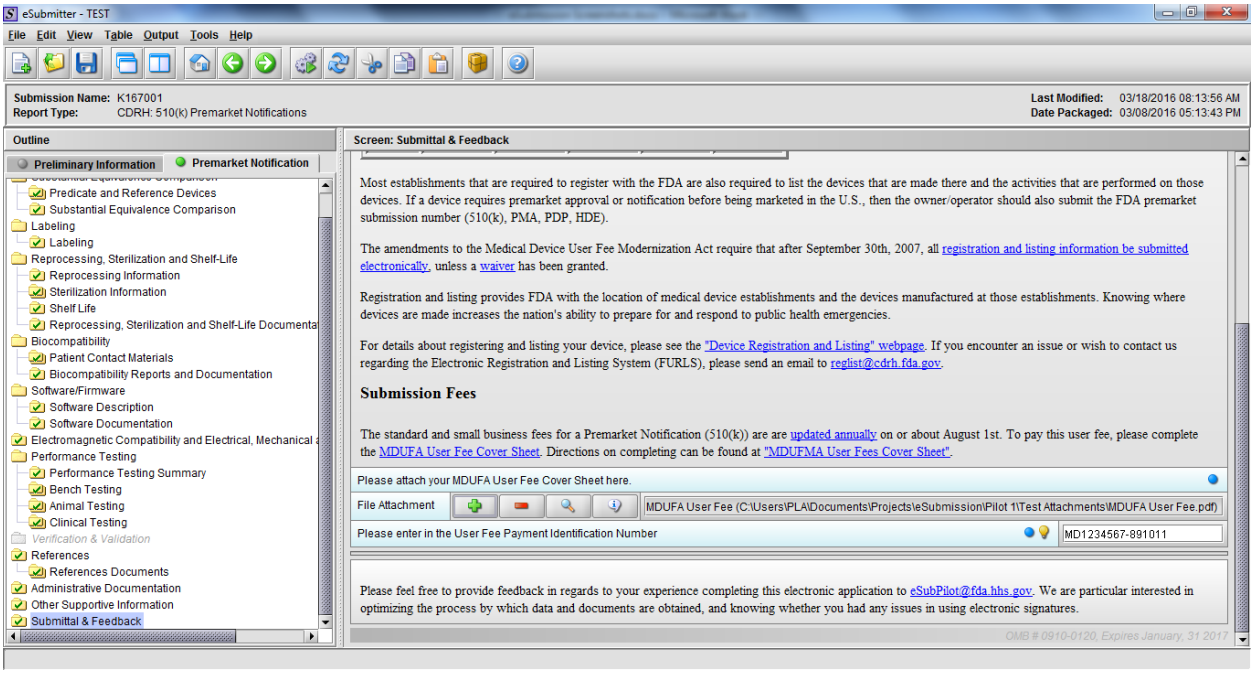
Registration and Listing
Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.
Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at "Who Must Register, List and Pay the Fee". There are no reductions in annual establishment registration fees for small businesses or any other group.
The schedule of registration fees for fiscal years as follows:
Year FY 2013 FY 2014 FY 2015 FY 2016 FY 2017
Fee $2,575 $3,313 $3,750 $3,872 $3.872
Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).
The amendments to the Medical Device User Fee Modernization Act require that after September 30th, 2007, all registration and listing information be submitted electronically, unless a waiver has been granted.
Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.
For details about registering and listing your device, please see the "Device Registration and Listing" webpage. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to reglist@cdrh.fda.gov.
Submission Fees


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: K167001
Report Type: CDRH: 510(k) Premarket Notifications
Last Modified: 03/18/2016 08:13:56 AM
Date Packaged: 03/08/2016 05:13:43 PM
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Submission Fees
The standard and small business fees for a Premarket Notification (510(k)) are are updated annually on or about August 1st. To pay this user fee, please complete the MDUFA User Fee Cover Sheet. Directions on completing can be found at "MDUFMA User Fees Cover Sheet".
Please attach your MDUFA User Fee Cover Sheet here.
File Attachment
MDUFA User Fee (C:\Users\PLA\Documents\Projects\eSubmission\Pilot 1\Test Attachments\MDUFA User Fee.pdf)
Please enter in the User Fee Payment Identification Number
MD1234567-891011
Please feel free to provide feedback in regards to your experience completing this electronic application to eSubPilot@fda.hhs.gov. We are particular interested in optimizing the process by which data and documents are obtained, and knowing whether you had any issues in using electronic signatures.
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