electronic Submission Template And Resource (eSTAR)

Draft Version 0.3 ()

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Introduction

This template is intended for use in both constructing a non-*in vitro* medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Question Marked Help Text Buttons** display regulatory information pertaining to that question or section when clicked. If a screen reader is used, stop dictation by pressing return.

2018-11-14T08:43:22 Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: What if I have several devices in one submission?
A: Wherever a question asks about a device, consider the question as it applies to any device within the submission.

Version History

Be sure you are using the latest version of this template when you submit it. If not, you may receive more additional information requests than you otherwise would.

0.3 (): Fixed minor bugs, submission fees info moved to help text, tabbing sequence issue resolved, animal-derived materials question added to Device Description (based on new guidance), message now advises deleting attachments not possible when eSTAR is signed, scripts password protected,
0.2 (2019-03-18): Biocompatibility Tests added. All dates now ISO 8601 standardized. Med Specialty alpha ordered by name not code. Phone/Fax number validations fixed. Bug preventing valid eSTAR from becoming invalid fixed. Bug preventing Pre-Submission Correspondence section from contributing to validation fixed. Type search works for Medical Specialty and Regulation dropdowns. IFU Form background no longer grainy.
0.1 (2019-01-07): Evaluation version, not for use.

Questions and feedback regarding this template can be sent to eSubPilot@fda.hhs.gov

Built by Patrick Axtell, FDA/CDRH Senior Tools and Template Engineer

Form FDA 4062 (3/19)

Application/Submission Type

Take care in providing answers and data to all of the questions in your submission. Any inaccurate or false information may be grounds for FDA to refuse to accept the application. FDA may refuse to accept if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewer what they are expecting (the EMC, Cybersecurity, and Wireless Technology sections have not been made complementary yet). This may reduce the number of inconsistencies and omissions in your application/submission, and therefore the number of additional information requests the FDA may send.

This template was reviewed and approved by the CDRH Quality Management Board, Tools and Templates Subcommittee.

Application Purpose

- (•) Premarket Notification 510(k)
- ( ) De Novo

?

Show Application Introduction

Application Type

- (•) Traditional
- ( ) Abbreviated
- ( ) Special

Show Application Type Introduction

Application Sub-Type

- (•) Original
- ( ) Supplement
- ( ) Amendment
- ( ) Report

?

Cover Letter

Add Attachment | Attach your Cover Letter | ?

Applicant Information

Contact

Title | Last Name | First Name

Email | Phone Number | Fax Number

Occupation Title

Company

Company Name

Address - Line 1

Address - Line 2

City | State | Zip | Country: United States of America

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? Yes ?

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

Submission Number | Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please also ensure the uploaded documentation identifies the location in the current submission where any issues are addressed.

Standards ?

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

Organization | Designation Number and Edition/Date | Recognition # | Delete Standard

Title

Are you using this standard for general use, or are you declaring conformity to it? ?

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2 ?

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

Trade Name	Model Number/Name	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	
Are there any direct or indirect patient contacting components?	Yes
• Is the device or a component an implant?	
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	

• Please check the attributes that are applicable to your device.

- ☐ Cloud Communication
- ☐ Network connection (active or not)
- ☐ Wireless communication in any form
- ☐ USB/serial ports/removable media
- ☐ Software upgrades (this includes patches)
- ☐ None of the above (Cybersecurity N/A)

Is the device or a component packaged as sterile?

The device/system uses or is... (choose all that apply)

- ☐ a single use device(s), non-sterile or packaged as sterile
- ☐ a single use device(s), terminal/end user sterilized
- ☐ a reusable single patient use device(s)
- ☐ a reusable multi-patient use device(s)

The environment of use of the device/system includes... (choose all that apply)

- ☐ Professional Healthcare Facility
- ☐ Home Environment
- ☐ Magnetic Resonance (MR) Environment
- ☐ Transport (Ambulatory) Environment
- ☐ Other Environment

Is the device a combination product?	
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	

Please check the attributes that are applicable to your device.

- ☐ Medical Counter Measures Device
- ☐ Nanotechnology
- ☐ Reprocessed Single Use Device
- ☐ Animal-Derived Material(s)

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 use the 510(k) summary produced 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). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Add Attachment — Device Description Documentation ?

Add Attachment — Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.

Components/Accessories/System

Is the device intended to be marketed with multiple components or accessories? Yes ?

Add Comp./Acc. — List all of the components and accessories to be marketed with the subject device.

Accessory/Component Identification — Delete Comp./Acc.

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). ?

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? ?

Add Attachment — Please attach Component / Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Classification

Add a primary regulation, primary product code, and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. ?

Medical Specialty

Regulation

Product Code

Associated Product Code(s) ?

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

Hover over each field on this page to view help text. It is recommended that you also include the age range for which your device(s) is indicated in your Indications for Use. Note that adults are considered 22 years old and greater (21 CFR 814.3(s)).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	
Predicate Submission Number (e.g., K180001)	
Predicate Device Trade Name	
Predicate Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	

Add Predicate/Reference Device

Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), 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 you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

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 you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. 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).	?

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1:2005(R)2012 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling. Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).		?
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?		?

Packaging and Shipping Labeling

Add Attachment	Please attach copies of packaging and shipping that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to: the device packaging, sterile packaging, boxes, and shipping containers.

Complementary Labeling

Add Attachment	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.

Specific Labeling

Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.		
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.		?

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.

Reprocessing, Sterility, and Shelf-Life

Since the answers you provided in the Device Description section indicate reprocessing and sterility information is needed, be aware that the Reprocessing section covers devices that are sterilized by the end user, while the Sterility section covers devices that are packaged as sterile.

Reprocessing

Reprocessing is defined as validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization. If the device(s) requires reprocessing, please consult the Reprocessing Guidance. Reprocessing documentation can be attached at the end of the "Reprocessing, Sterility, and Shelf-Life" section.

Are cleaning or disinfection or sterilization instructions included in the labeling?	
How many different sets of reprocessing instructions are included (maximum of 4):	1

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.	

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	

Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.		?
Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., “no visual contamination”), and 3) steps the user should repeat if the endpoint is not met.		?
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.		?
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.		?
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.		?

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	Sterilization & high level disinfection and/or liquid chemical sterilization

Sterilization

Please specifically cite the attachment(s) and page number(s) where the instructions recommend the use of an FDA-cleared or legally marketed wrap, pouch, or other method of maintaining sterility?		?

For steam sterilization: Please specifically cite the attachment(s) and page number(s) where the instructions describe the general method (e.g., gravity or pre-vacuum) and all critical sterilization cycle specifications (time, temperature, and dry time). Type "N/A" if not applicable. View help text for more information.		?
For ethylene oxide: Please specifically cite the attachment(s) and page number(s) where the instructions describe the sterilization cycle parameters. Type "N/A" if not applicable. View help text for more information.		?
Other sterilization methods: Please specifically cite the attachment(s) and page number(s) where the instructions describe the sterilization methods to enable the user to implement the cycle (e.g., sterilizer make, model, and cycle name for hydrogen peroxide cycles). Type "N/A" if not applicable.		?
Post-process handling: Please specifically cite the attachment(s) and page number(s) where the instructions include the aeration time for removal of residual sterilants. Type "N/A" if not applicable.		?
High-Level Disinfection/Liquid Chemical Sterilization		
Please specifically cite the attachment(s) and page number(s) where the instructions recommend use of an FDA-cleared high-level disinfectant (HLD) or liquid chemical sterilant (LCS).		?
Please specifically cite the attachment(s) and page number(s) where the instructions recommend following HLD/LCS manufacturer's instructions.		?
Please specifically cite the attachment(s) and page number(s) where the instructions recommend complete immersion in HLD/LCS solution, including contact with all lumens.		?
Please specifically cite the attachment(s) and page number(s) where the instructions include instructions for rinsing, drying, and storage.		?
Technically Feasible, Understandable, and Comprehensive		?

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled “Non-sterile” directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If

you are unsure, check if similar devices have labeling with this type of warning.

Sterility

How many sterilization methods are there (maximum of 4)? 1 ?

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized. ?

What is the Sterilization Method? ?

What standard(s) were used for validation? ?

What is the Sterility Assurance Level (SAL)?

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? ?

Please provide a description of the packaging, the materials used, and a description of the package test methods. ?

Guidance and Special Controls Adherence

If you choose to use an alternative approach in comparison to what is stated in the applicable sterility guidance or special controls, please provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?		Yes
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.

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device.	?

Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Patient Contacting Materials

How many patient contacting products/components/materials are there? 1

Patient Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the patient.

Please state the exact name and any identifiable information for the particular material used.

If color additives are included, please identify them here.

Choose intended contact of the particular material.

Please provide the submission number (e.g., K010001) if you are aware of a previous device using the same material with similar nature of contact.

Choose the type of tissue contact of your patient contacting material.

Duration of Contact

Is there a potential for repeat exposure?

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the material is identical in formulation and processing to predicate material) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.**

Biocompatibility Reports and Documentation

Add Attachment

Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software and cybersecurity information is needed.

Software

Software Level of Concern (LOC) Determination ?

Does the Software qualify as Blood Establishment Computer Software? ?	
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software 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 control a life supporting or life sustaining function? b) Does the Software 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 control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software 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 provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	

Software Description ?

Add Attachment	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).

Software Documentation

The following software documentation is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Add Attachment	Device Hazard Analysis	?
Add Attachment	Software Requirements Specifications (SRS)	?
Add Attachment	Architecture Design Chart	?
Add Attachment	Software Design Specifications (SDS)	?
Add Attachment	Traceability Analysis/Matrix	?
Add Attachment	Software Development Environment Description	?
Add Attachment	Verification & Validation Testing	?
Add Attachment	Revision Level History	?
Add Attachment	Unresolved Anomalies	?
	Cybersecurity	?
Add Attachment	Please attach documentation pertaining to Cybersecurity & Interoperability below. Click the blue help text button for guidance on whether documentation is recommended for your device. If documentation is not recommended, please attach a justification describing why cybersecurity and/or Interoperability documentation is not applicable.	

EMC, Wireless, Electrical, Mechanical and Thermal Safety

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

EMC, Wireless & EMT Summary

Please summarize the Electromagnetic Compatibility Testing, Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing, Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to demonstrate substantial equivalence?	Yes
Was Animal Testing used in order to demonstrate substantial equivalence?	Yes
Was Clinical Testing used in order to demonstrate substantial equivalence?	Yes

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced 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(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES 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. ?

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 subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.) ?

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above. ?

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

Add Attachment

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.

Animal Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

Add Attachment	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.	
Add Attachment	Please include a study protocol which includes all elements as outlined in 21 CFR 58.120.	?
Add Attachment	Please include a final study report which includes all elements as outlined in 21 CFR 58.185.	?

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. ?

Clinical Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

Add Attachment	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.

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.

References

Is literature referenced in the submission?

Administrative Documentation

Add Attachment	Financial Certification and Disclosure Statement (Form FDA-3454)	?
Add Attachment	Clinical Trials Certification Form (Form FDA-3674)	?
Add Attachment	Executive Summary	?

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 your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will yo be electronically signing this application for submission?	
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary can be produced for you. If you choose to submit a 510(k) Summary instead of 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. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	

Add Attachment	Please attach your User Fee form here.	?
	Please enter in the User Fee Payment Identification Number.	?

Show User Fee Introduction

Verification

The following sections are complete:
Application/Submission Type
EMC, Wireless, Electrical, Mechanical and Thermal Safety

The following sections are incomplete:
Cover Letter
Administrative Information
Device Description
Indications for Use
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
Performance Testing
References
Administrative Documentation

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 the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

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).

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 website. 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.

Submittal Directions

Quality in 510(k) Review Pilot

We are planning to accept eSTAR submissions as part of the Quality in 510(k) Review pilot in the near future. Until then be sure to use the 510(k) eSubmitter template for the pilot instead, information for which can be found on the pilot website.