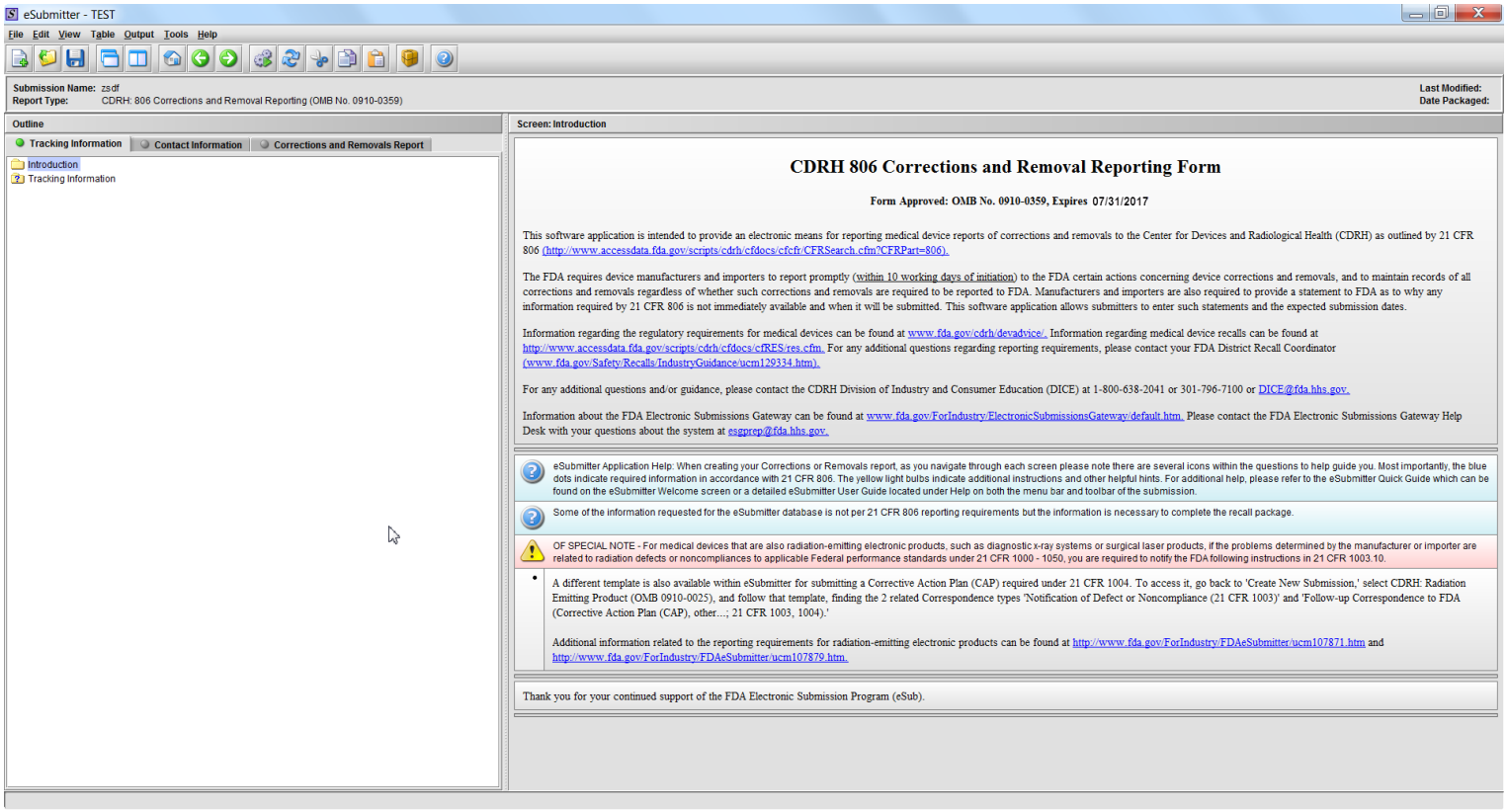
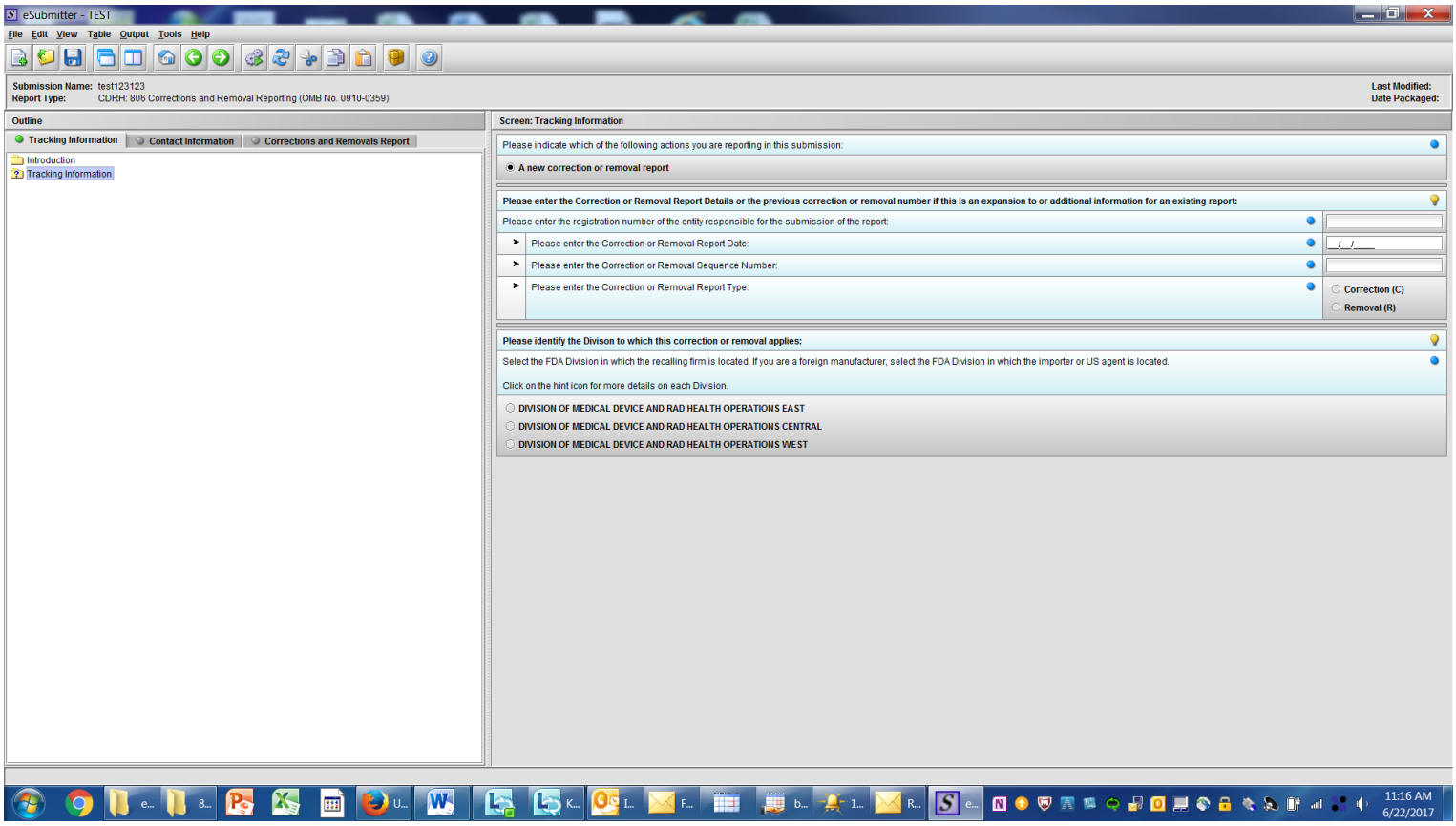
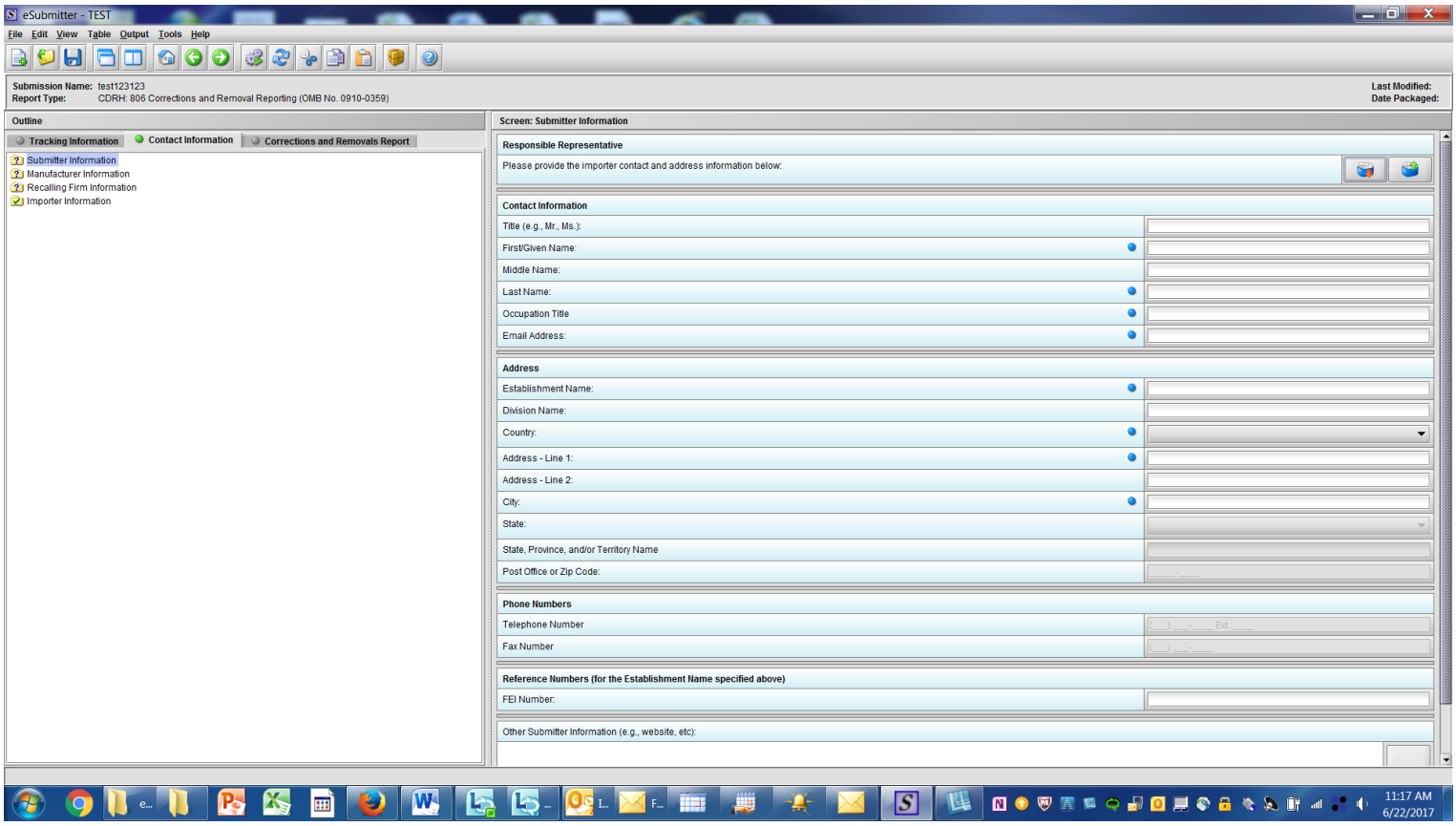
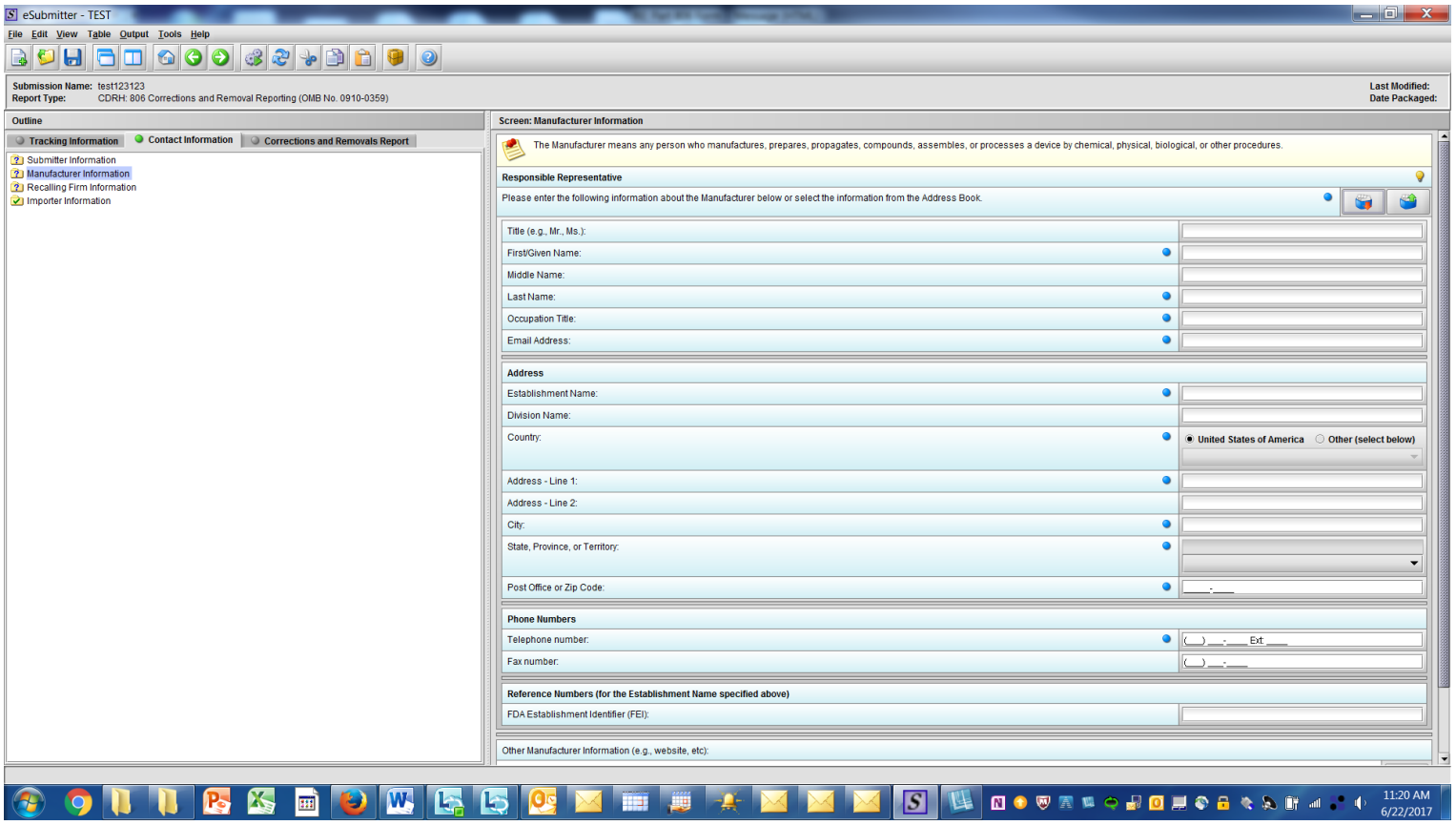
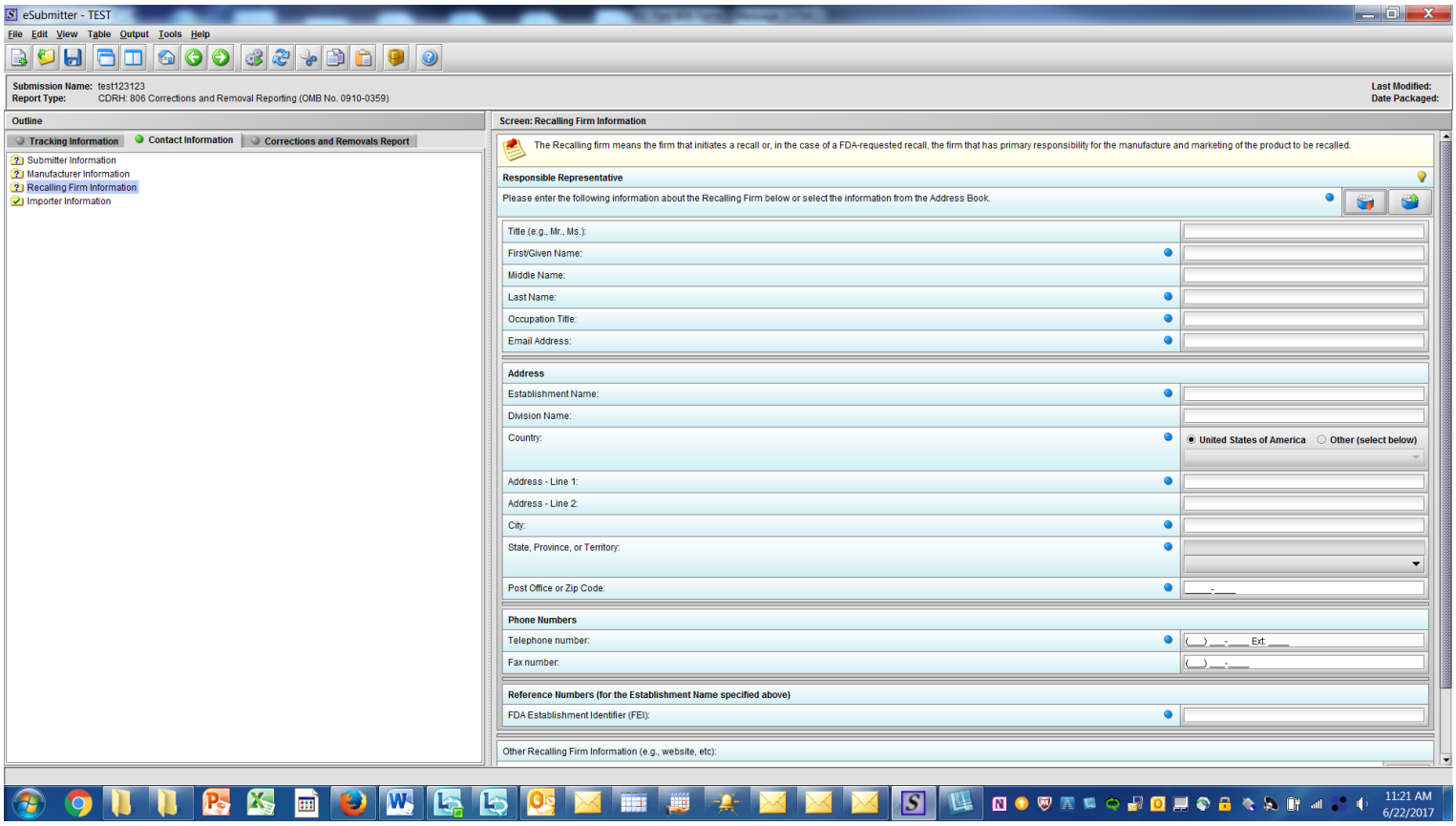
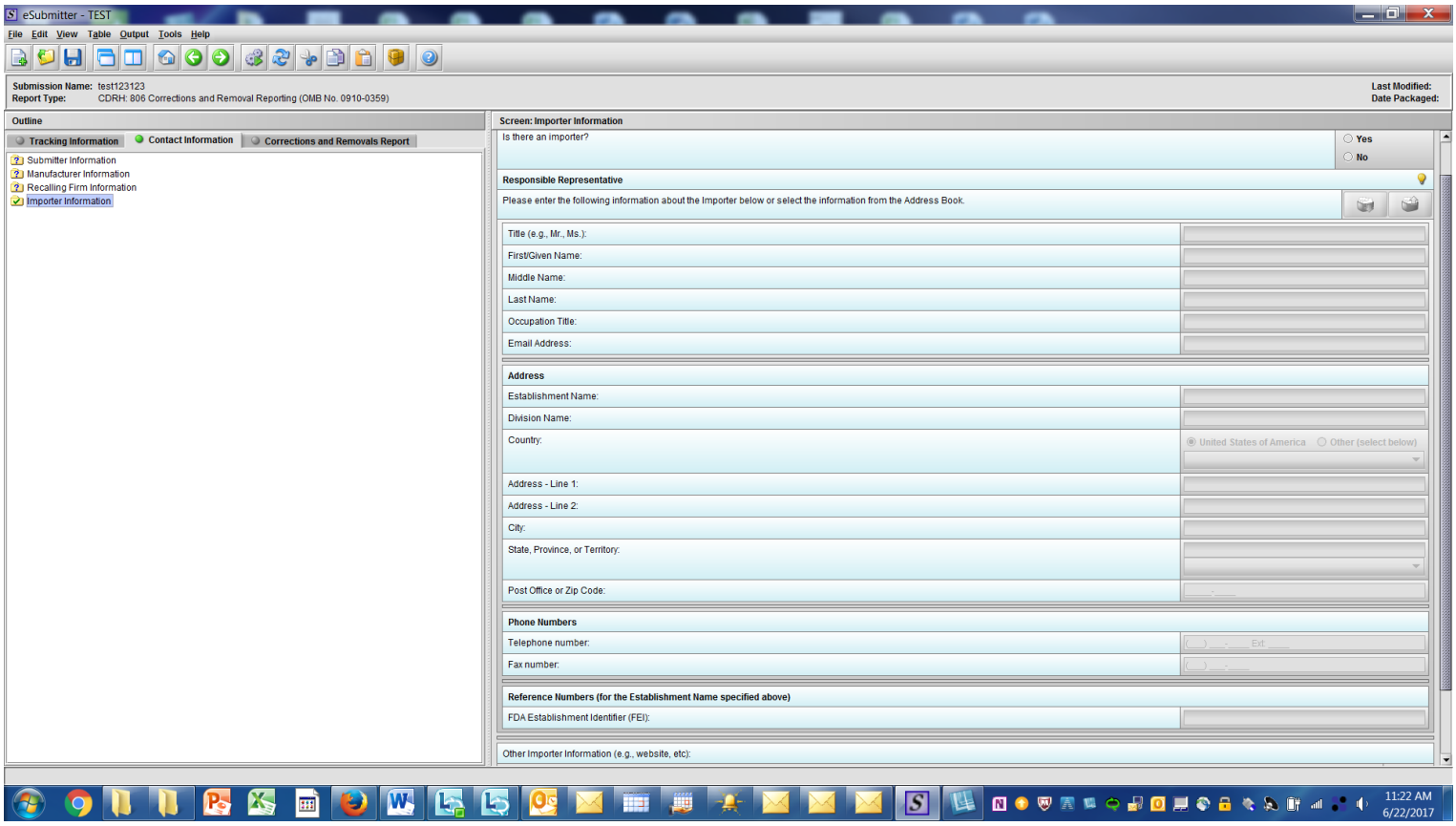

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: zsdf
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Introduction
Tracking Information
Screen: Introduction
CDRH 806 Corrections and Removal Reporting Form
Form Approved: OMB No. 0910-0359, Expires 07/31/2017
This software application is intended to provide an electronic means for reporting medical device reports of corrections and removals to the Center for Devices and Radiological Health (CDRH) as outlined by 21 CFR 806 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806).
The FDA requires device manufacturers and importers to report promptly (within 10 working days of initiation) to the FDA certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. Manufacturers and importers are also required to provide a statement to FDA as to why any information required by 21 CFR 806 is not immediately available and when it will be submitted. This software application allows submitters to enter such statements and the expected submission dates.
Information regarding the regulatory requirements for medical devices can be found at www.fda.gov/cdrh/devadvice/. Information regarding medical device recalls can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm. For any additional questions regarding reporting requirements, please contact your FDA District Recall Coordinator (www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm).
For any additional questions and/or guidance, please contact the CDRH Division of Industry and Consumer Education (DICE) at 1-800-638-2041 or 301-796-7100 or DICE@fda.hhs.gov.
Information about the FDA Electronic Submissions Gateway can be found at www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. Please contact the FDA Electronic Submissions Gateway Help Desk with your questions about the system at esgprep@fda.hhs.gov.
eSubmitter Application Help: When creating your Corrections or Removals report, as you navigate through each screen please note there are several icons within the questions to help guide you. Most importantly, the blue dots indicate required information in accordance with 21 CFR 806. The yellow light bulbs indicate additional instructions and other helpful hints. For additional help, please refer to the eSubmitter Quick Guide which can be found on the eSubmitter Welcome screen or a detailed eSubmitter User Guide located under Help on both the menu bar and toolbar of the submission.
Some of the information requested for the eSubmitter database is not per 21 CFR 806 reporting requirements but the information is necessary to complete the recall package.
OF SPECIAL NOTE - For medical devices that are also radiation-emitting electronic products, such as diagnostic x-ray systems or surgical laser products, if the problems determined by the manufacturer or importer are related to radiation defects or noncompliances to applicable Federal performance standards under 21 CFR 1000 - 1050, you are required to notify the FDA following instructions in 21 CFR 1003.10.
A different template is also available within eSubmitter for submitting a Corrective Action Plan (CAP) required under 21 CFR 1004. To access it, go back to 'Create New Submission,' select CDRH: Radiation Emitting Product (OMB 0910-0025), and follow that template, finding the 2 related Correspondence types 'Notification of Defect or Noncompliance (21 CFR 1003)' and 'Follow-up Correspondence to FDA (Corrective Action Plan (CAP), other…; 21 CFR 1003, 1004).'
Additional information related to the reporting requirements for radiation-emitting electronic products can be found at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107871.htm and http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107879.htm.
Thank you for your continued support of the FDA Electronic Submission Program (eSub).

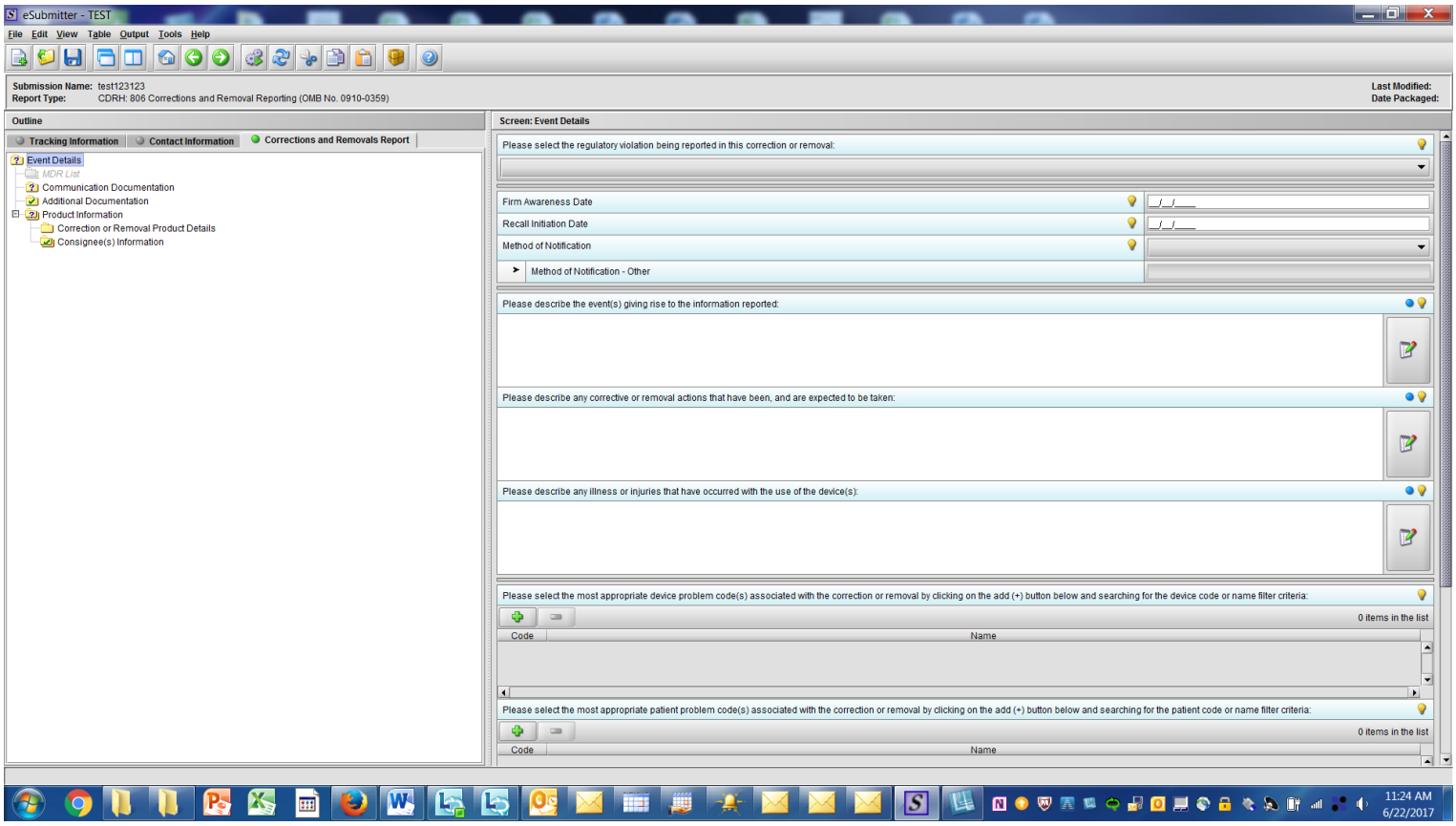

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Introduction
Tracking Information
Screen: Tracking Information
Please indicate which of the following actions you are reporting in this submission:
A new correction or removal report
Please enter the Correction or Removal Report Details or the previous correction or removal number if this is an expansion to or additional information for an existing report:
Please enter the registration number of the entity responsible for the submission of the report:
Please enter the Correction or Removal Report Date:
__/__/____
Please enter the Correction or Removal Sequence Number:
Please enter the Correction or Removal Report Type:
Correction (C)
Removal (R)
Please identify the Divison to which this correction or removal applies:
Select the FDA Division in which the recalling firm is located. If you are a foreign manufacturer, select the FDA Division in which the importer or US agent is located.
Click on the hint icon for more details on each Division.
DIVISION OF MEDICAL DEVICE AND RAD HEALTH OPERATIONS EAST
DIVISION OF MEDICAL DEVICE AND RAD HEALTH OPERATIONS CENTRAL
DIVISION OF MEDICAL DEVICE AND RAD HEALTH OPERATIONS WEST
11:16 AM
6/22/2017

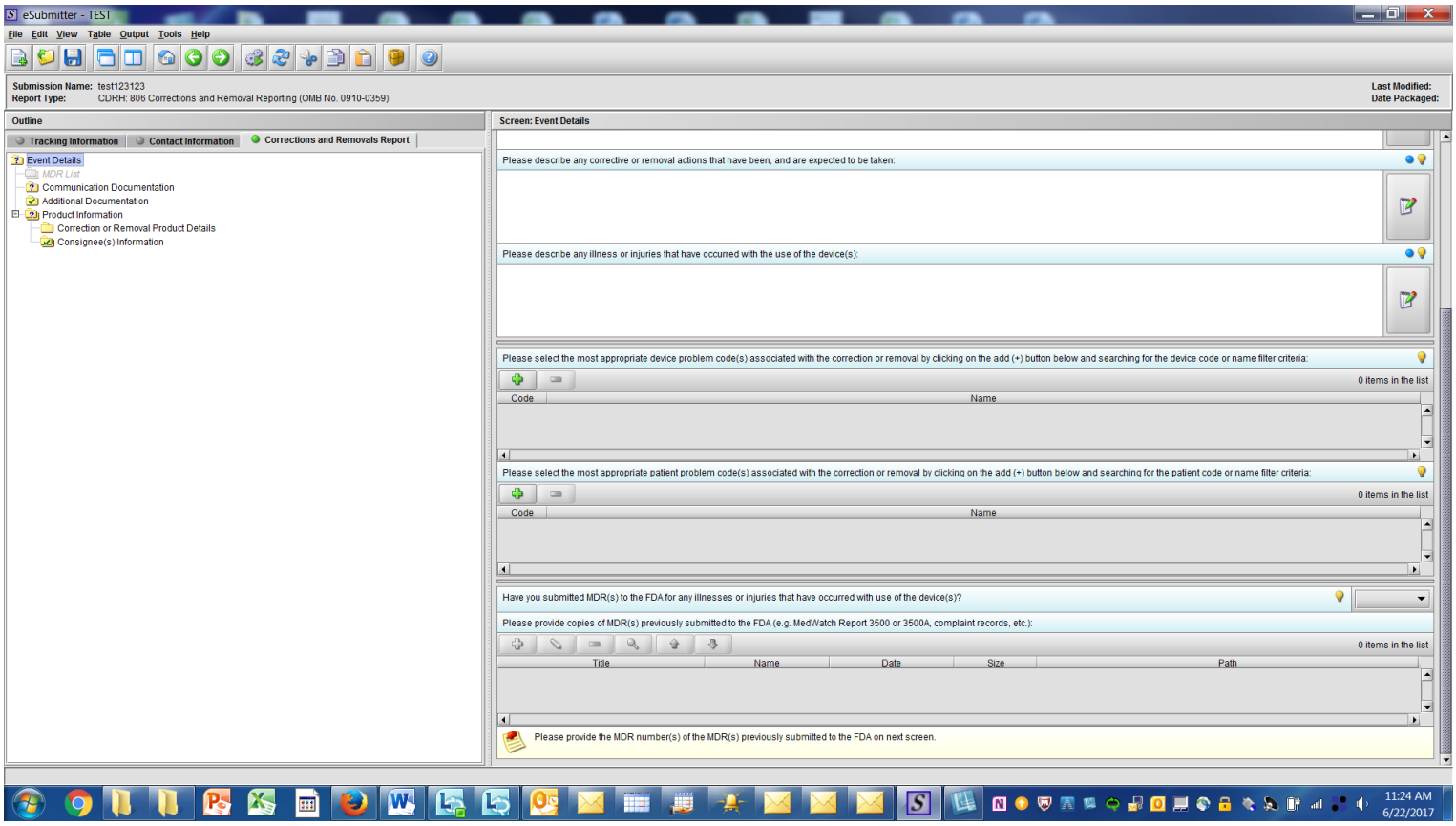

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Submitter Information
Manufacturer Information
Recalling Firm Information
Importer Information
Screen: Submitter Information
Responsible Representative
Please provide the importer contact and address information below:
Contact Information
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title
Email Address:
Address
Establishment Name:
Division Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, and/or Territory Name
Post Office or Zip Code:
Phone Numbers
Telephone Number
Fax Number
Reference Numbers (for the Establishment Name specified above)
FEI Number:
Other Submitter Information (e.g., website, etc):
11:17 AM
6/22/2017

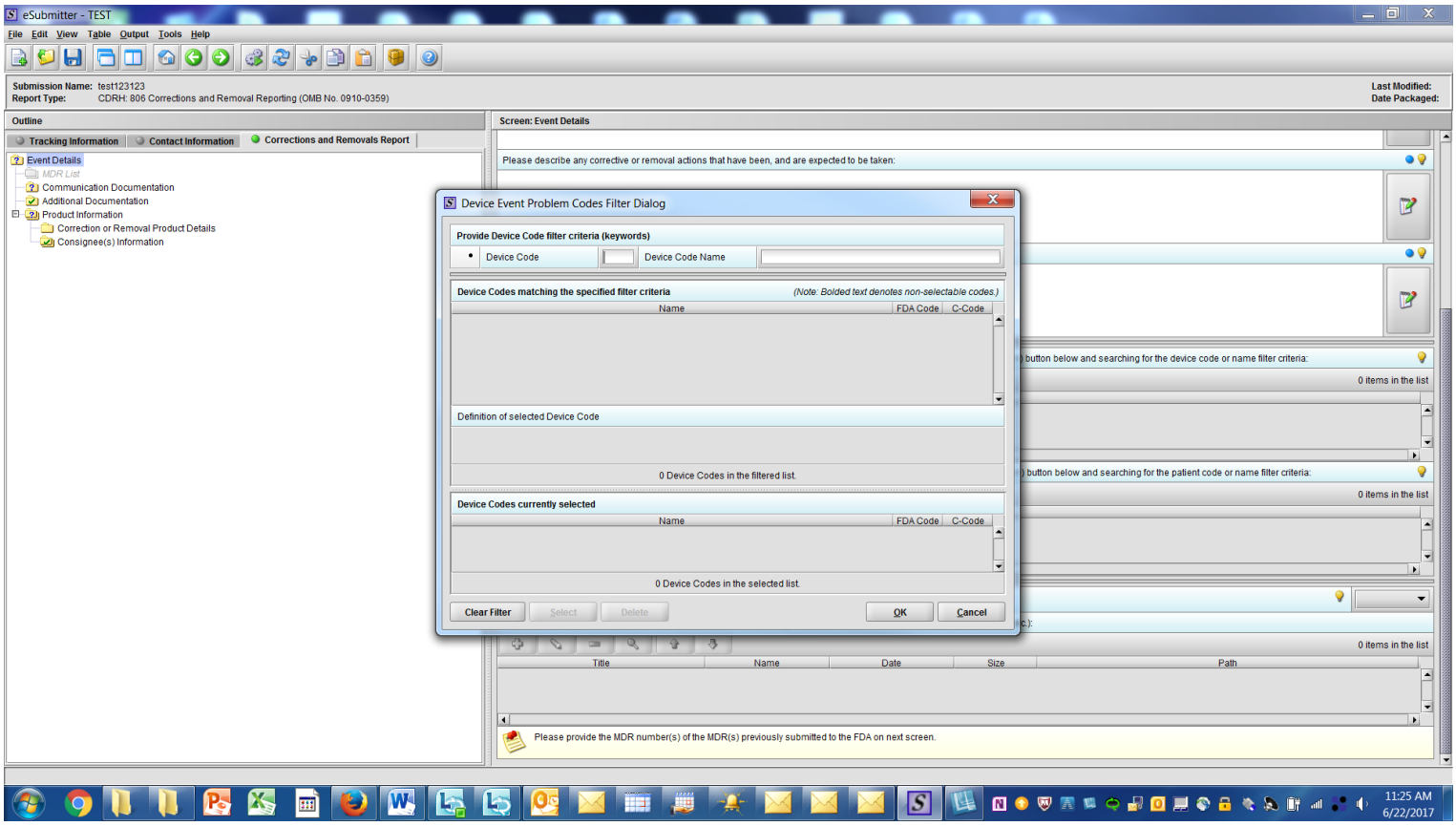

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Submitter Information
Manufacturer Information
Recalling Firm Information
Importer Information
Screen: Manufacturer Information
The Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.
Responsible Representative
Please enter the following information about the Manufacturer below or select the information from the Address Book.
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title:
Email Address:
Address
Establishment Name:
Division Name:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
Ext:
Fax number:
Reference Numbers (for the Establishment Name specified above)
FDA Establishment Identifier (FEI):
Other Manufacturer Information (e.g., website, etc):
11:20 AM
6/22/2017

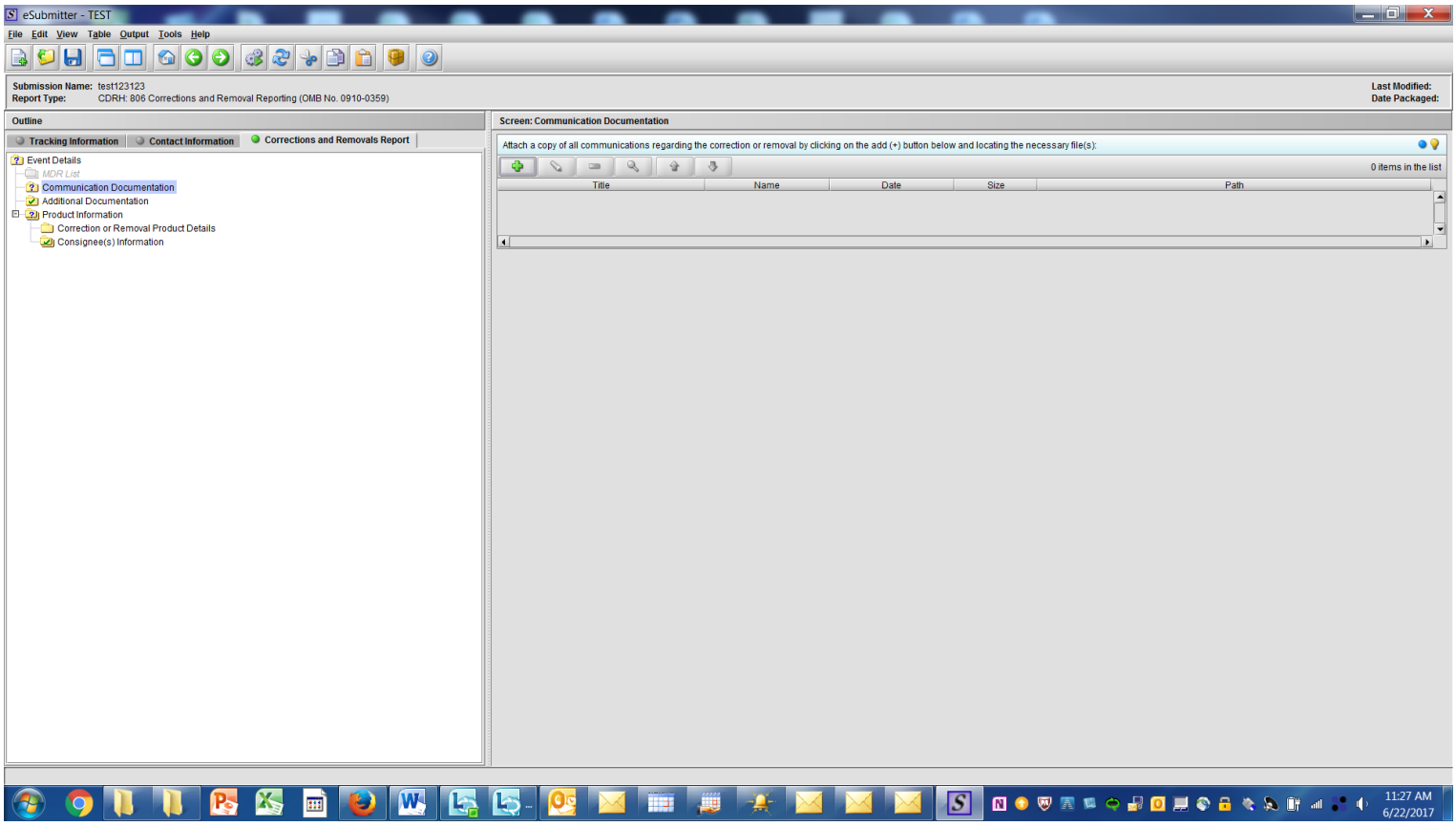

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Submitter Information
Manufacturer Information
Recalling Firm Information
Importer Information
Screen: Recalling Firm Information
The Recalling firm means the firm that initiates a recall or, in the case of a FDA-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
Responsible Representative
Please enter the following information about the Recalling Firm below or select the information from the Address Book.
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title:
Email Address:
Address
Establishment Name:
Division Name:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
Ext:
Fax number:
Reference Numbers (for the Establishment Name specified above)
FDA Establishment Identifier (FEI):
Other Recalling Firm Information (e.g., website, etc):
11:21 AM
6/22/2017

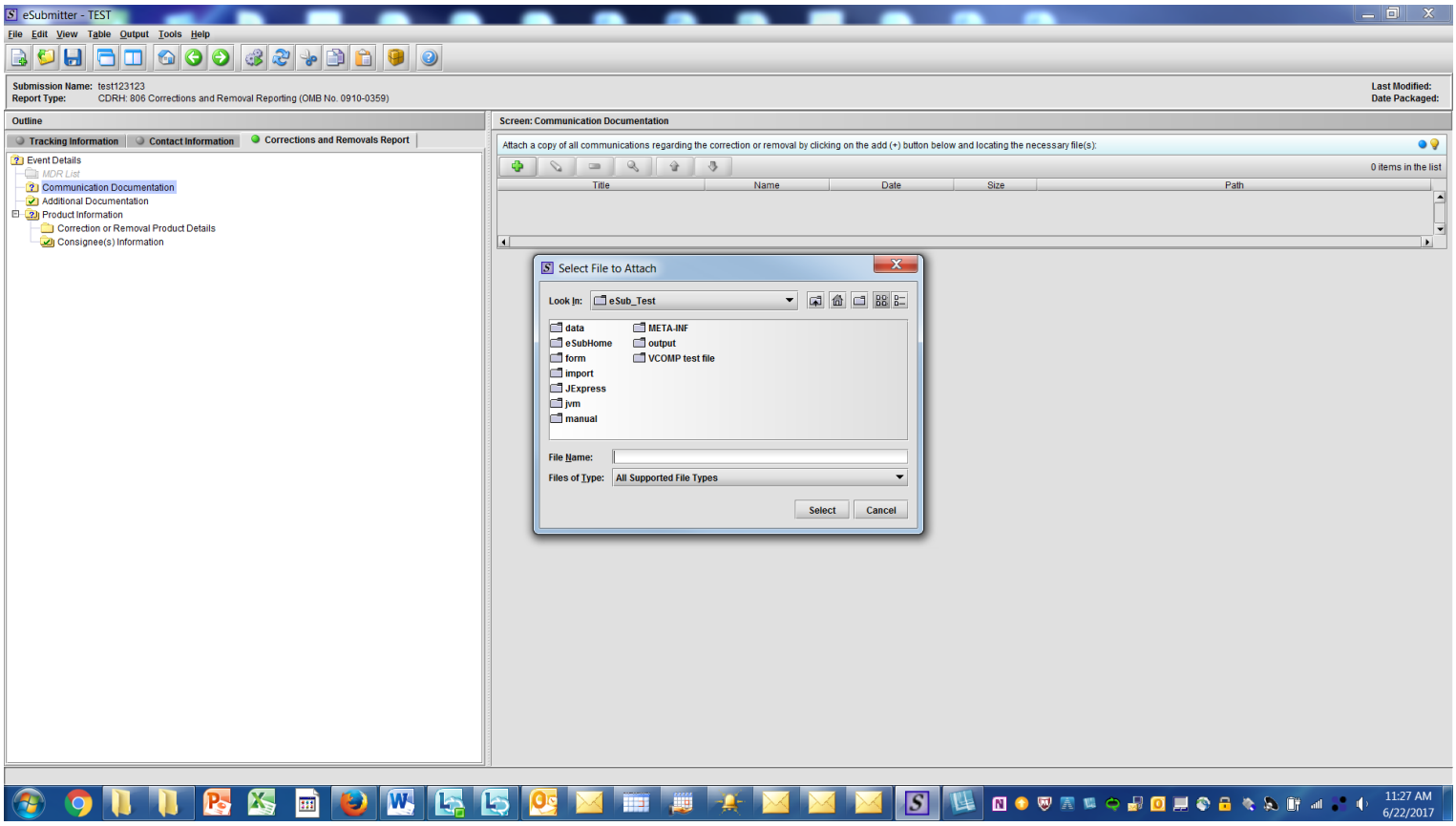

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Submitter Information
Manufacturer Information
Recalling Firm Information
Importer Information
Screen: Importer Information
Is there an importer?
Yes
No
Responsible Representative
Please enter the following information about the Importer below or select the information from the Address Book.
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Occupation Title:
Email Address:
Address
Establishment Name:
Division Name:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
Fax number:
Reference Numbers (for the Establishment Name specified above)
FDA Establishment Identifier (FEI):
Other Importer Information (e.g., website, etc):
11:22 AM
6/22/2017

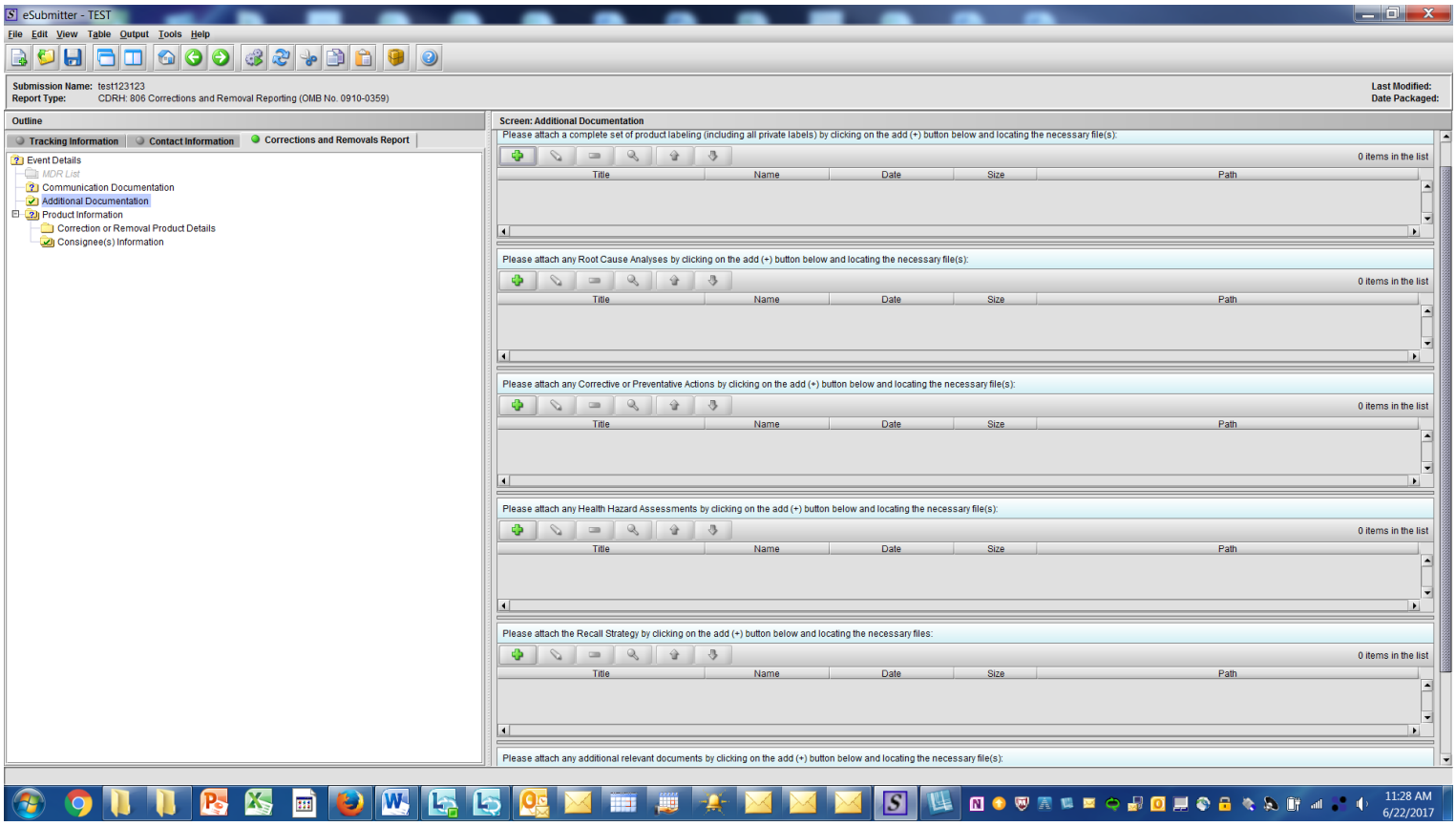

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Event Details
Please select the regulatory violation being reported in this correction or removal:
Firm Awareness Date
Recall Initiation Date
Method of Notification
Method of Notification - Other
Please describe the event(s) giving rise to the information reported:
Please describe any corrective or removal actions that have been, and are expected to be taken:
Please describe any illness or injuries that have occurred with the use of the device(s):
Please select the most appropriate device problem code(s) associated with the correction or removal by clicking on the add (+) button below and searching for the device code or name filter criteria:
0 items in the list
Code
Name
Please select the most appropriate patient problem code(s) associated with the correction or removal by clicking on the add (+) button below and searching for the patient code or name filter criteria:
0 items in the list
Code
Name
11:24 AM
6/22/2017

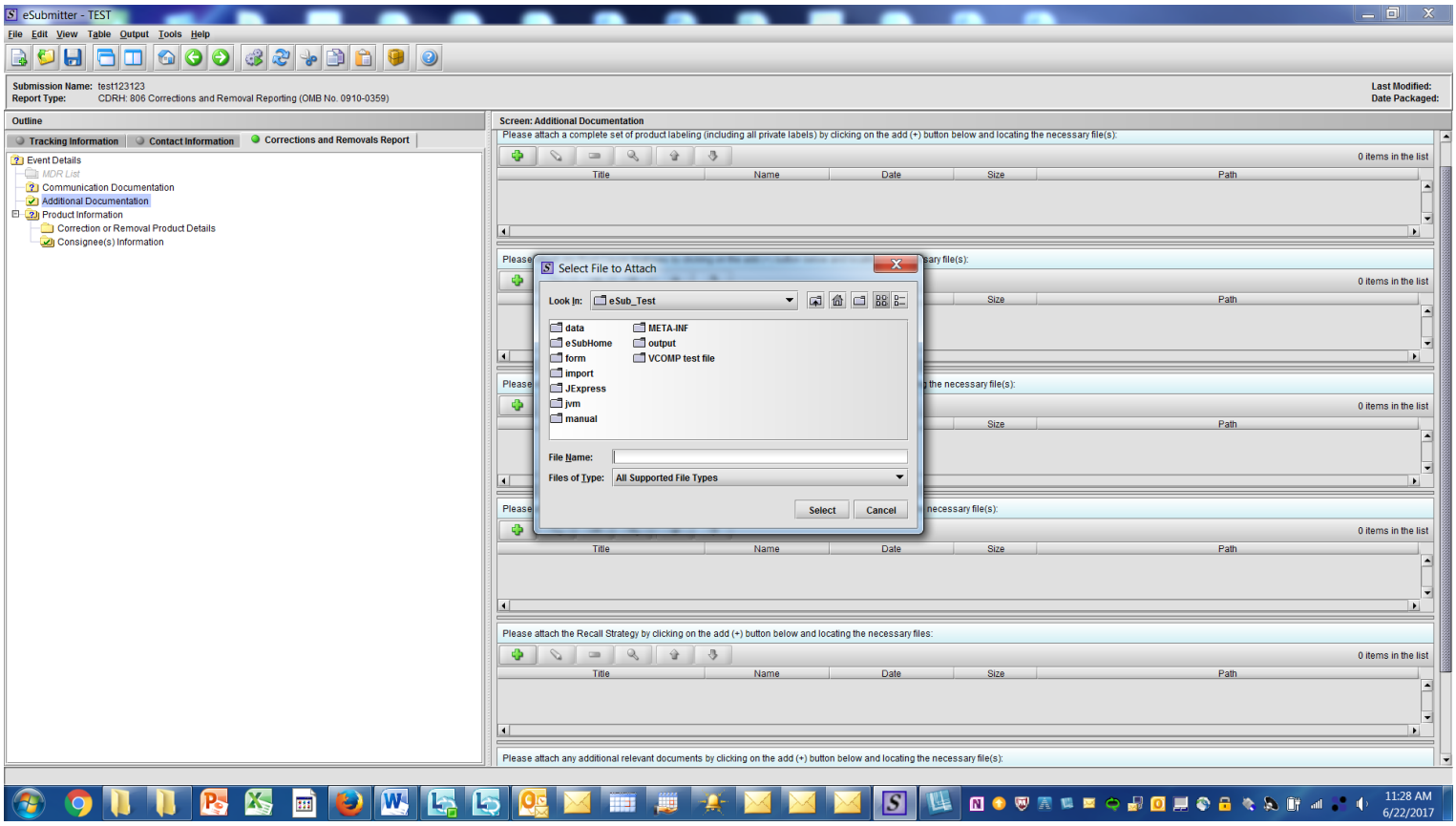

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Event Details
Please describe any corrective or removal actions that have been, and are expected to be taken:
Please describe any illness or injuries that have occurred with the use of the device(s):
Please select the most appropriate device problem code(s) associated with the correction or removal by clicking on the add (+) button below and searching for the device code or name filter criteria:
0 items in the list
Code
Name
Please select the most appropriate patient problem code(s) associated with the correction or removal by clicking on the add (+) button below and searching for the patient code or name filter criteria:
0 items in the list
Code
Name
Have you submitted MDR(s) to the FDA for any illnesses or injuries that have occurred with use of the device(s)?
Please provide copies of MDR(s) previously submitted to the FDA (e.g. MedWatch Report 3500 or 3500A, complaint records, etc.):
0 items in the list
Title
Name
Date
Size
Path
Please provide the MDR number(s) of the MDR(s) previously submitted to the FDA on next screen.
11:24 AM
6/22/2017

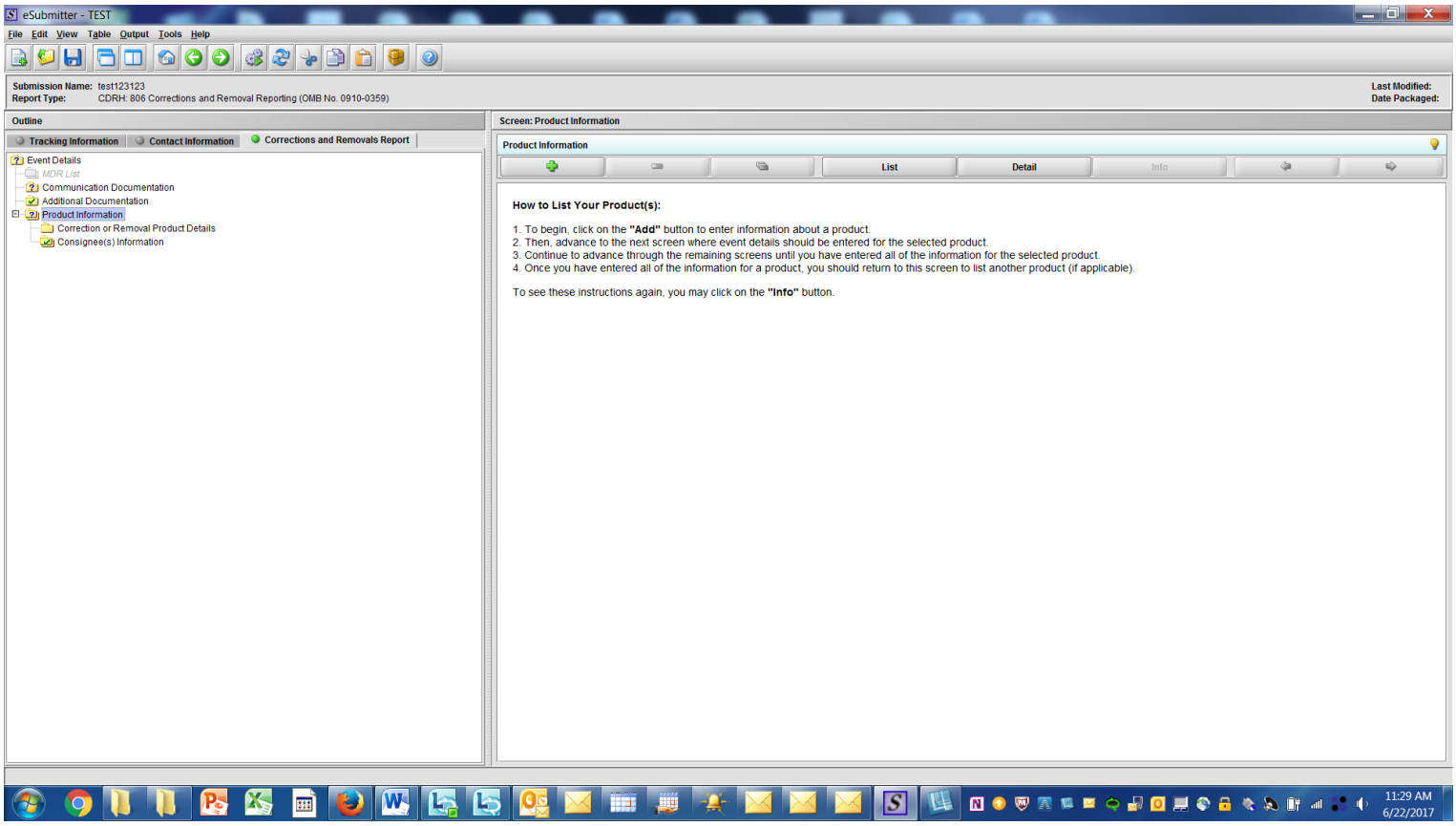

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Event Details
Please describe any corrective or removal actions that have been, and are expected to be taken:
Device Event Problem Codes Filter Dialog
Provide Device Code filter criteria (keywords)
Device Code
Device Code Name
Device Codes matching the specified filter criteria
(Note: Bolded text denotes non-selectable codes.)
Name
FDA Code
C-Code
Definition of selected Device Code
0 Device Codes in the filtered list.
Device Codes currently selected
Name
FDA Code
C-Code
0 Device Codes in the selected list.
Clear Filter
Select
Delete
OK
Cancel
button below and searching for the device code or name filter criteria:
0 items in the list
button below and searching for the patient code or name filter criteria:
0 items in the list
0 items in the list
Title
Name
Date
Size
Path
Please provide the MDR number(s) of the MDR(s) previously submitted to the FDA on next screen.
11:25 AM
6/22/2017

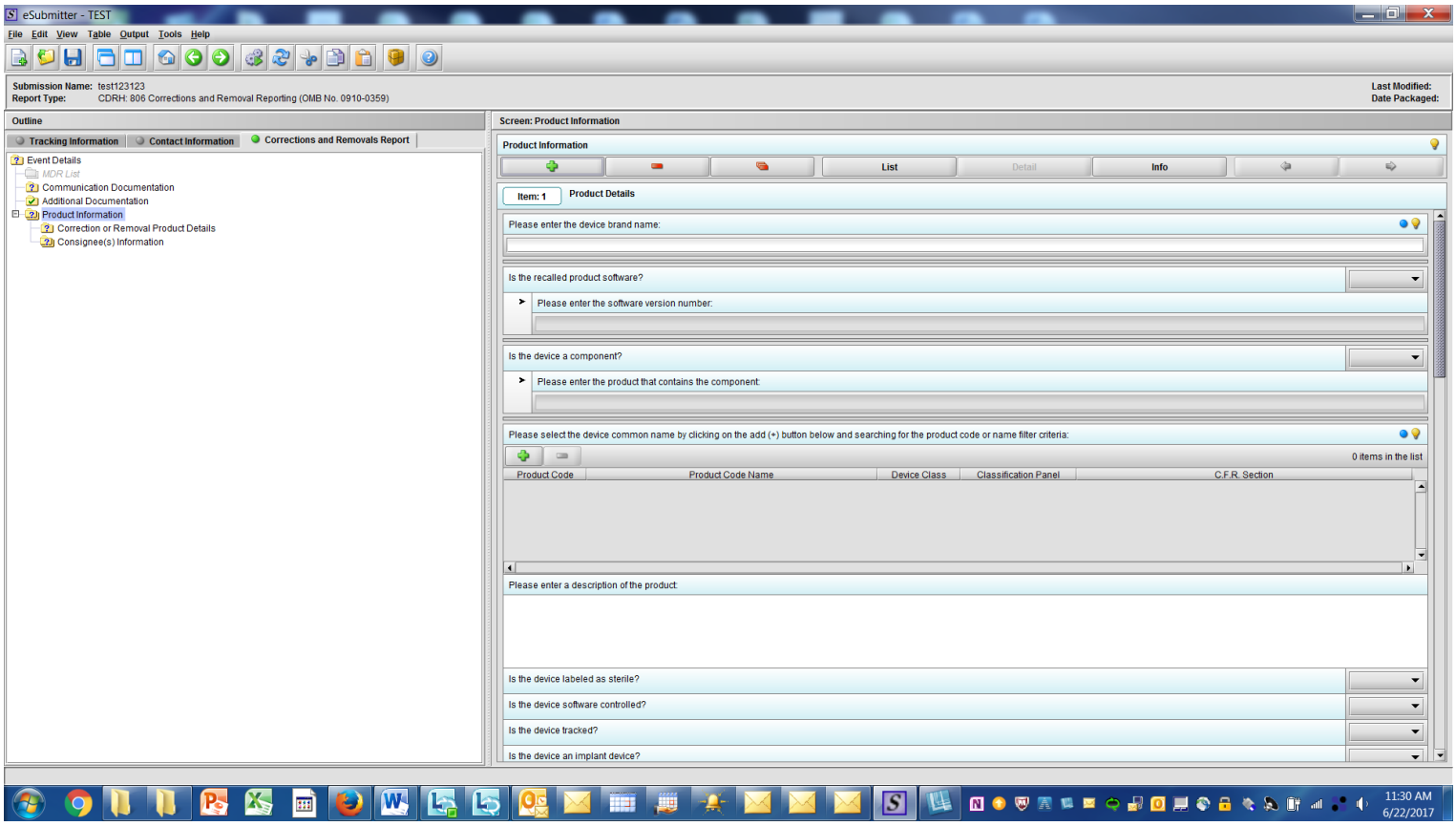

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Communication Documentation
Attach a copy of all communications regarding the correction or removal by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Title
Name
Date
Size
Path
11:27 AM
6/22/2017

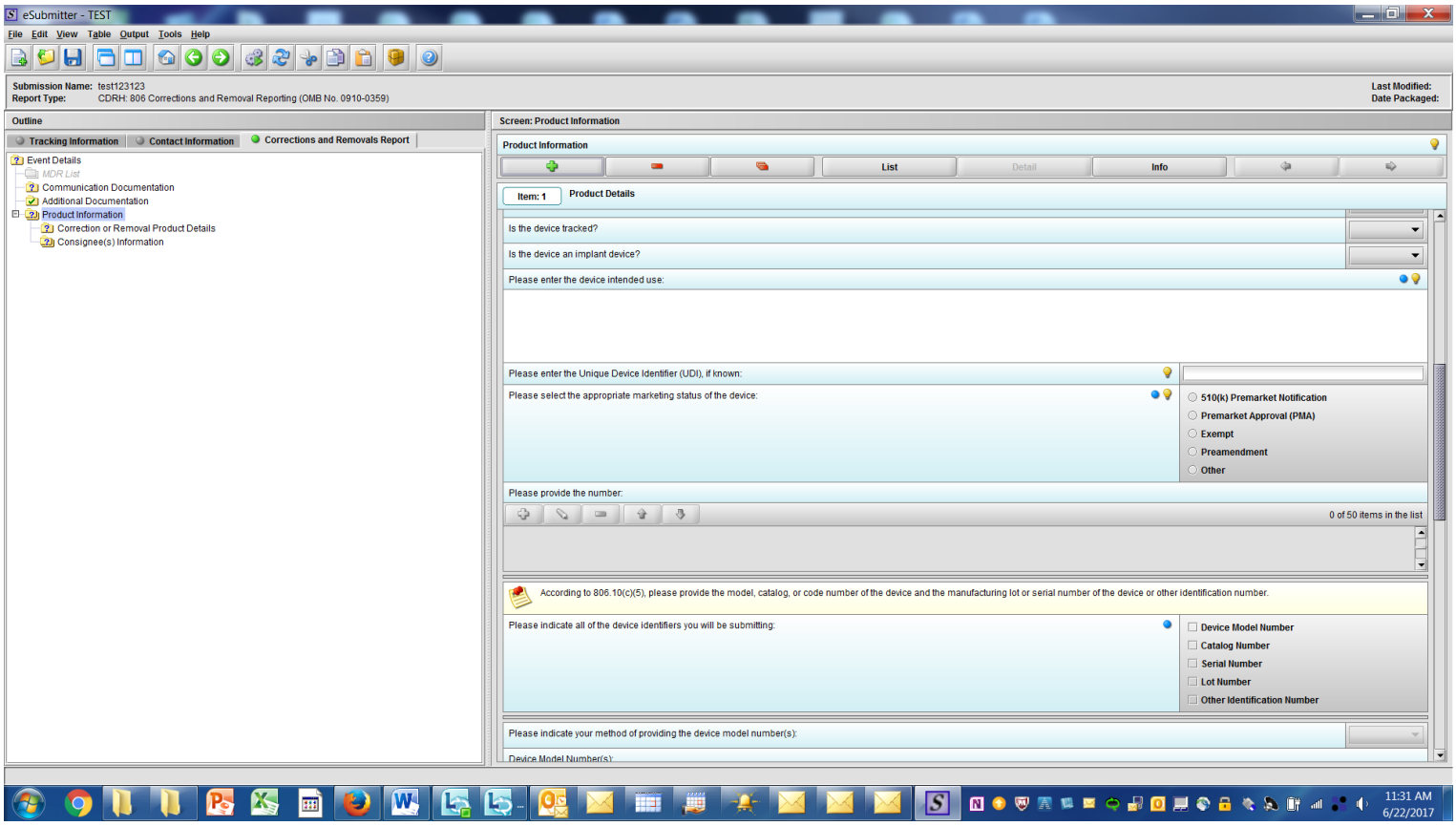

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Communication Documentation
Attach a copy of all communications regarding the correction or removal by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Title
Name
Date
Size
Path
Select File to Attach
Look In:
eSub_Test
data
eSubHome
form
import
JExpress
jvm
manual
META-INF
output
VCOMP test file
File Name:
Files of Type:
All Supported File Types
Select
Cancel
11:27 AM
6/22/2017

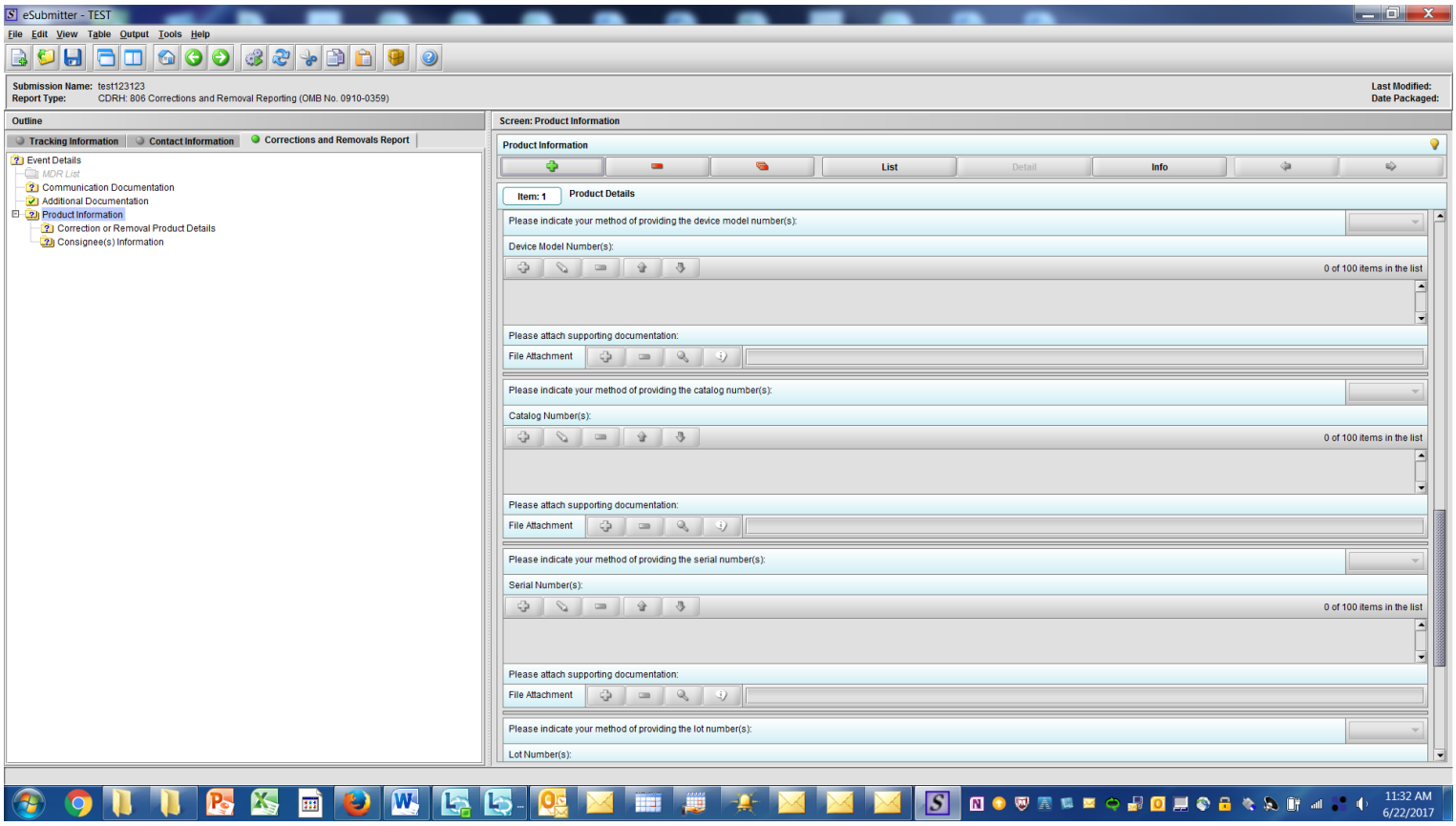

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Additional Documentation
Please attach a complete set of product labeling (including all private labels) by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Title
Name
Date
Size
Path
Please attach any Root Cause Analyses by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Please attach any Corrective or Preventative Actions by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Please attach any Health Hazard Assessments by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Please attach the Recall Strategy by clicking on the add (+) button below and locating the necessary files:
0 items in the list
Please attach any additional relevant documents by clicking on the add (+) button below and locating the necessary file(s):
11:28 AM
6/22/2017

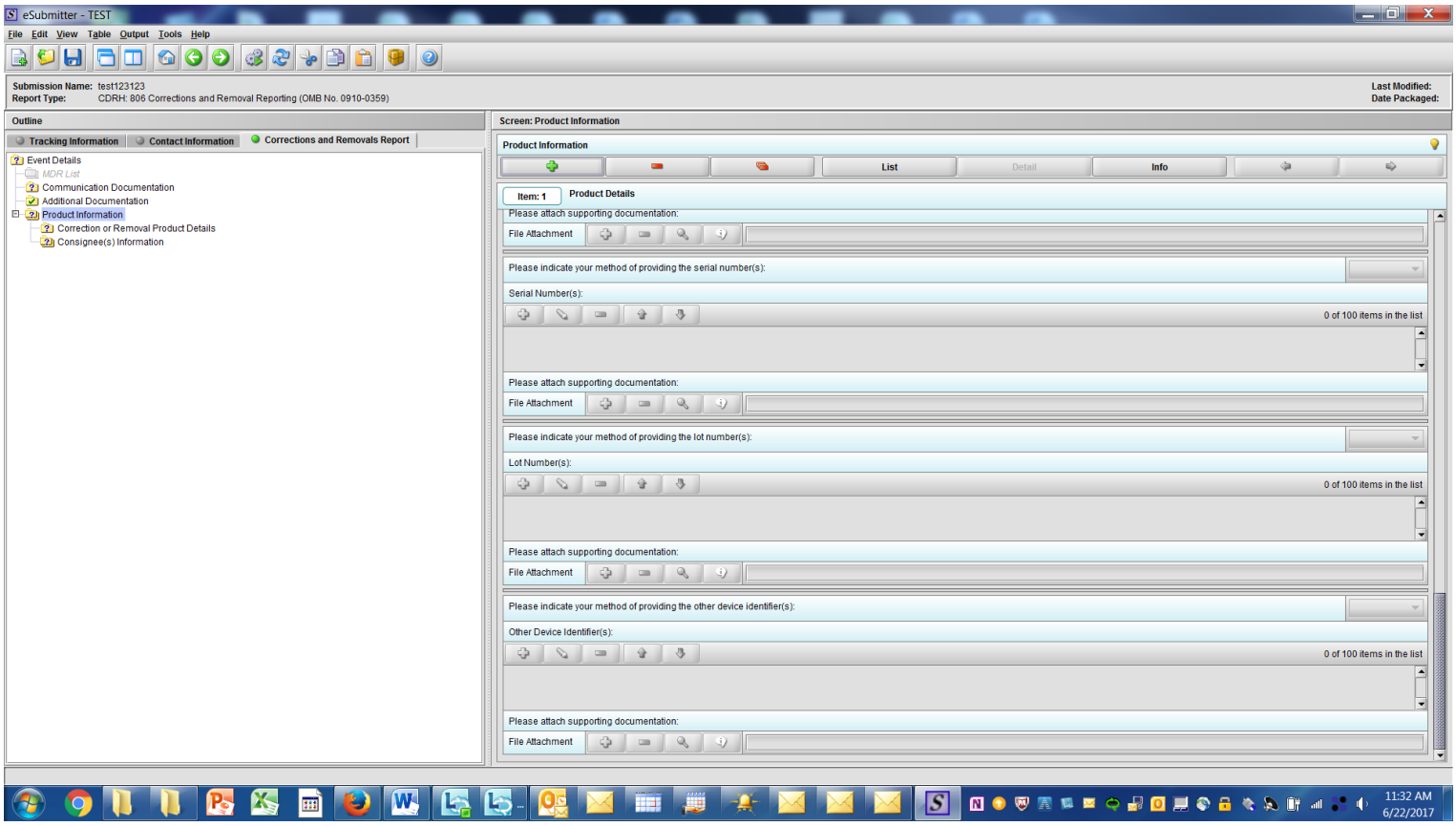

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Additional Documentation
Please attach a complete set of product labeling (including all private labels) by clicking on the add (+) button below and locating the necessary file(s):
0 items in the list
Title
Name
Date
Size
Path
Select File to Attach
Look In:
eSub_Test
data
eSubHome
form
import
JExpress
jvm
manual
META-INF
output
VCOMP test file
File Name:
Files of Type:
All Supported File Types
Select
Cancel
Please attach the Recall Strategy by clicking on the add (+) button below and locating the necessary files:
Please attach any additional relevant documents by clicking on the add (+) button below and locating the necessary file(s):
11:28 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Product Information
Product Information
List
Detail
Info
How to List Your Product(s):
1. To begin, click on the "Add" button to enter information about a product.
2. Then, advance to the next screen where event details should be entered for the selected product.
3. Continue to advance through the remaining screens until you have entered all of the information for the selected product.
4. Once you have entered all of the information for a product, you should return to this screen to list another product (if applicable).
To see these instructions again, you may click on the "Info" button.
11:29 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Product Information
Product Information
List
Detail
Info
Item: 1
Product Details
Please enter the device brand name:
Is the recalled product software?
Please enter the software version number:
Is the device a component?
Please enter the product that contains the component:
Please select the device common name by clicking on the add (+) button below and searching for the product code or name filter criteria:
0 items in the list
Product Code
Product Code Name
Device Class
Classification Panel
C.F.R. Section
Please enter a description of the product:
Is the device labeled as sterile?
Is the device software controlled?
Is the device tracked?
Is the device an implant device?
11:30 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Product Information
Product Information
List
Detail
Info
Item: 1
Product Details
Is the device tracked?
Is the device an implant device?
Please enter the device intended use:
Please enter the Unique Device Identifier (UDI), if known:
Please select the appropriate marketing status of the device:
510(k) Premarket Notification
Premarket Approval (PMA)
Exempt
Preamendment
Other
Please provide the number:
0 of 50 items in the list
According to 806.10(c)(5), please provide the model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
Please indicate all of the device identifiers you will be submitting:
Device Model Number
Catalog Number
Serial Number
Lot Number
Other Identification Number
Please indicate your method of providing the device model number(s):
Device Model Number(s):
11:31 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Product Information
Product Information
List
Detail
Info
Item: 1
Product Details
Please indicate your method of providing the device model number(s):
Device Model Number(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the catalog number(s):
Catalog Number(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the serial number(s):
Serial Number(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the lot number(s):
Lot Number(s):
11:32 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
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Product Information
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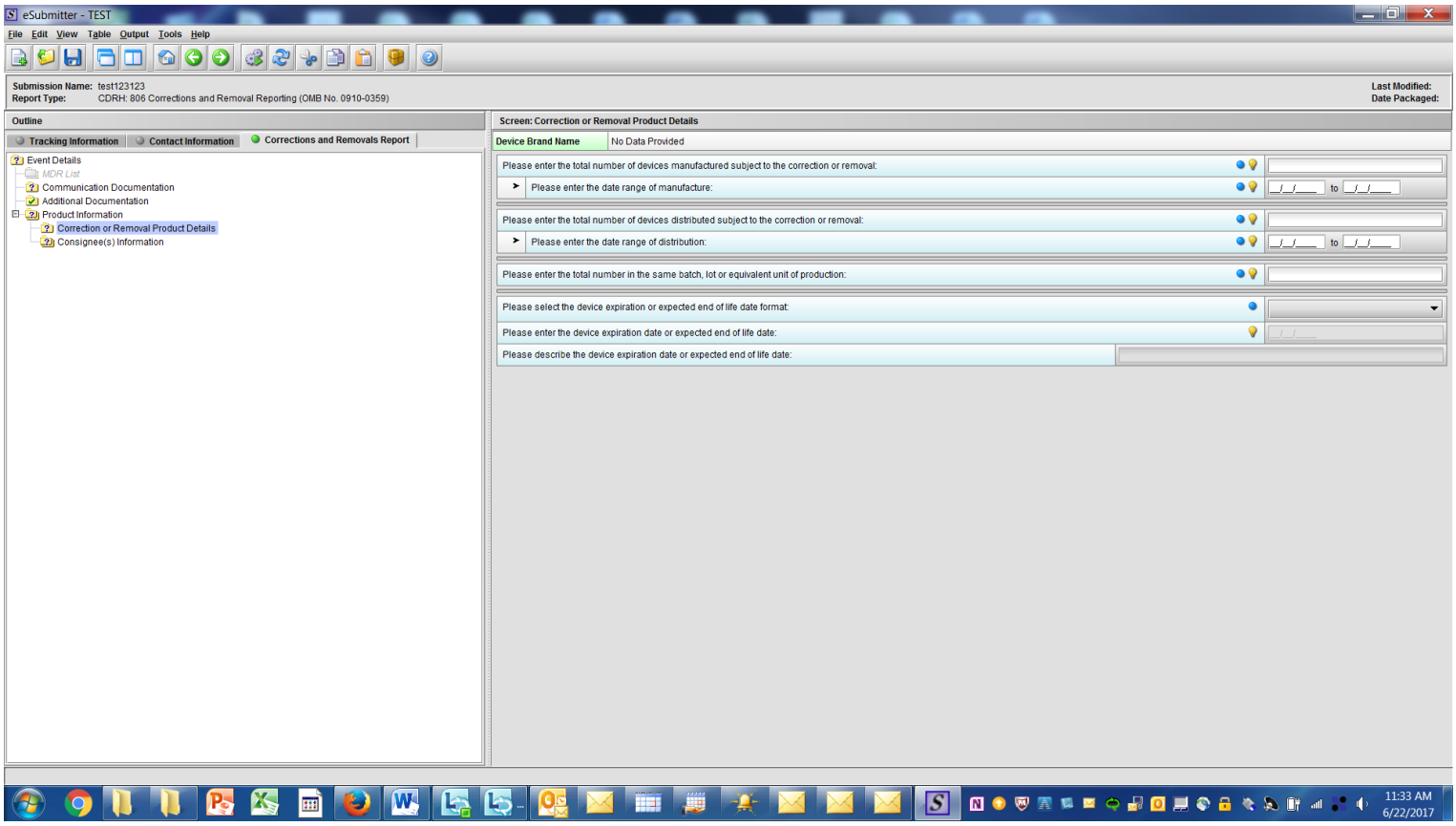
Consignee(s) Information
Screen: Product Information
Product Information
List
Detail
Info
Item: 1
Product Details
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the serial number(s):
Serial Number(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the lot number(s):
Lot Number(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
Please indicate your method of providing the other device identifier(s):
Other Device Identifier(s):
0 of 100 items in the list
Please attach supporting documentation:
File Attachment
11:32 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
Date Packaged:
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Tracking Information
Contact Information
Corrections and Removals Report
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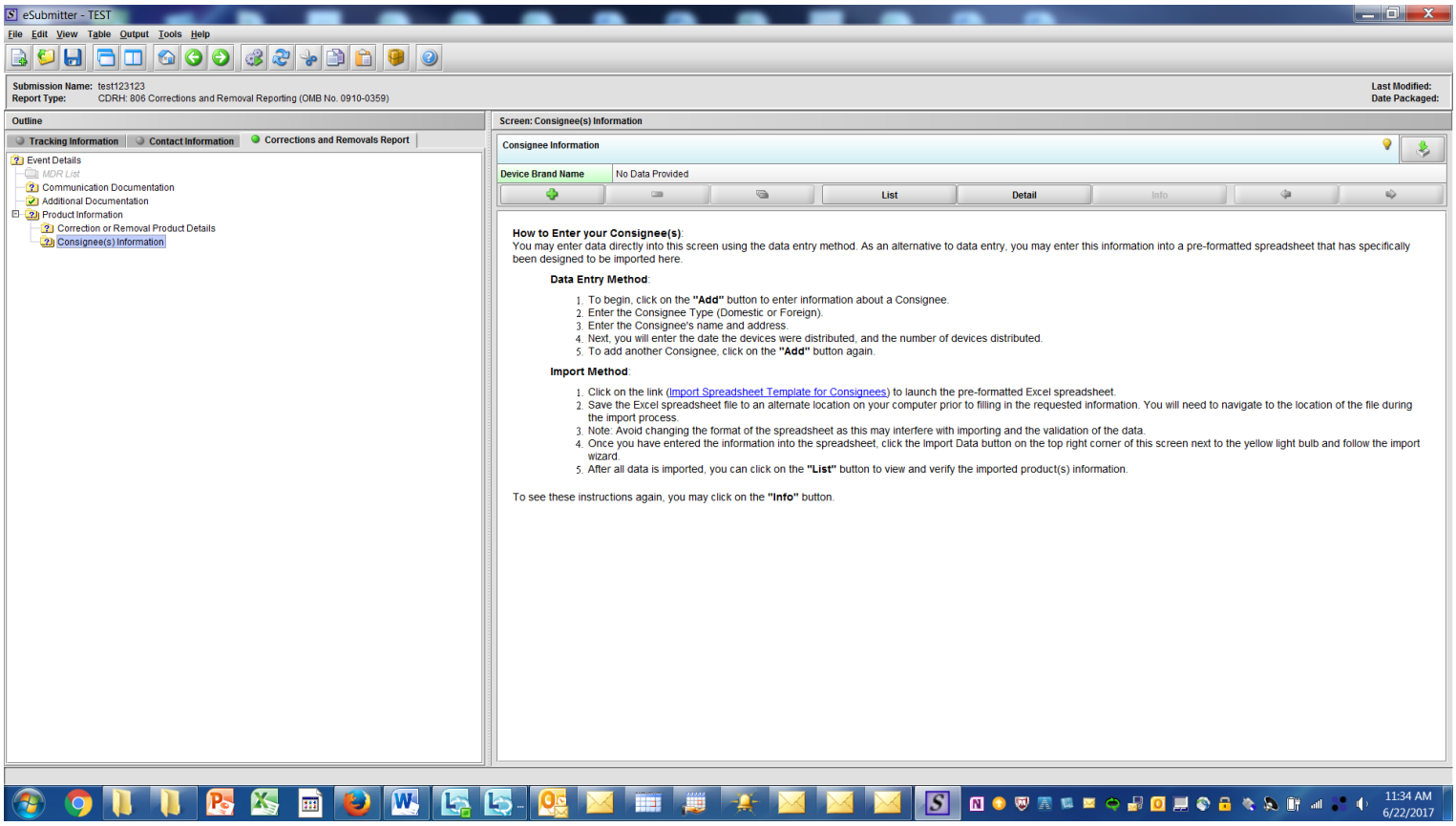
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Correction or Removal Product Details
Device Brand Name
No Data Provided
Please enter the total number of devices manufactured subject to the correction or removal:
Please enter the date range of manufacture:
__/__/____ to __/__/____
Please enter the total number of devices distributed subject to the correction or removal:
Please enter the date range of distribution:
__/__/____ to __/__/____
Please enter the total number in the same batch, lot or equivalent unit of production:
Please select the device expiration or expected end of life date format:
Please enter the device expiration date or expected end of life date:
__/__/____
Please describe the device expiration date or expected end of life date:
11:33 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
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Outline
Tracking Information
Contact Information
Corrections and Removals Report
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Consignee(s) Information
Consignee Information
Device Brand Name
No Data Provided
List
Detail
Info
How to Enter your Consignee(s):
You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that has specifically been designed to be imported here.
Data Entry Method:
1. To begin, click on the "Add" button to enter information about a Consignee.
2. Enter the Consignee Type (Domestic or Foreign).
3. Enter the Consignee's name and address.
4. Next, you will enter the date the devices were distributed, and the number of devices distributed.
5. To add another Consignee, click on the "Add" button again.
Import Method:
1. Click on the link (Import Spreadsheet Template for Consignees) to launch the pre-formatted Excel spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen next to the yellow light bulb and follow the import wizard.
5. After all data is imported, you can click on the "List" button to view and verify the imported product(s) information.
To see these instructions again, you may click on the "Info" button.
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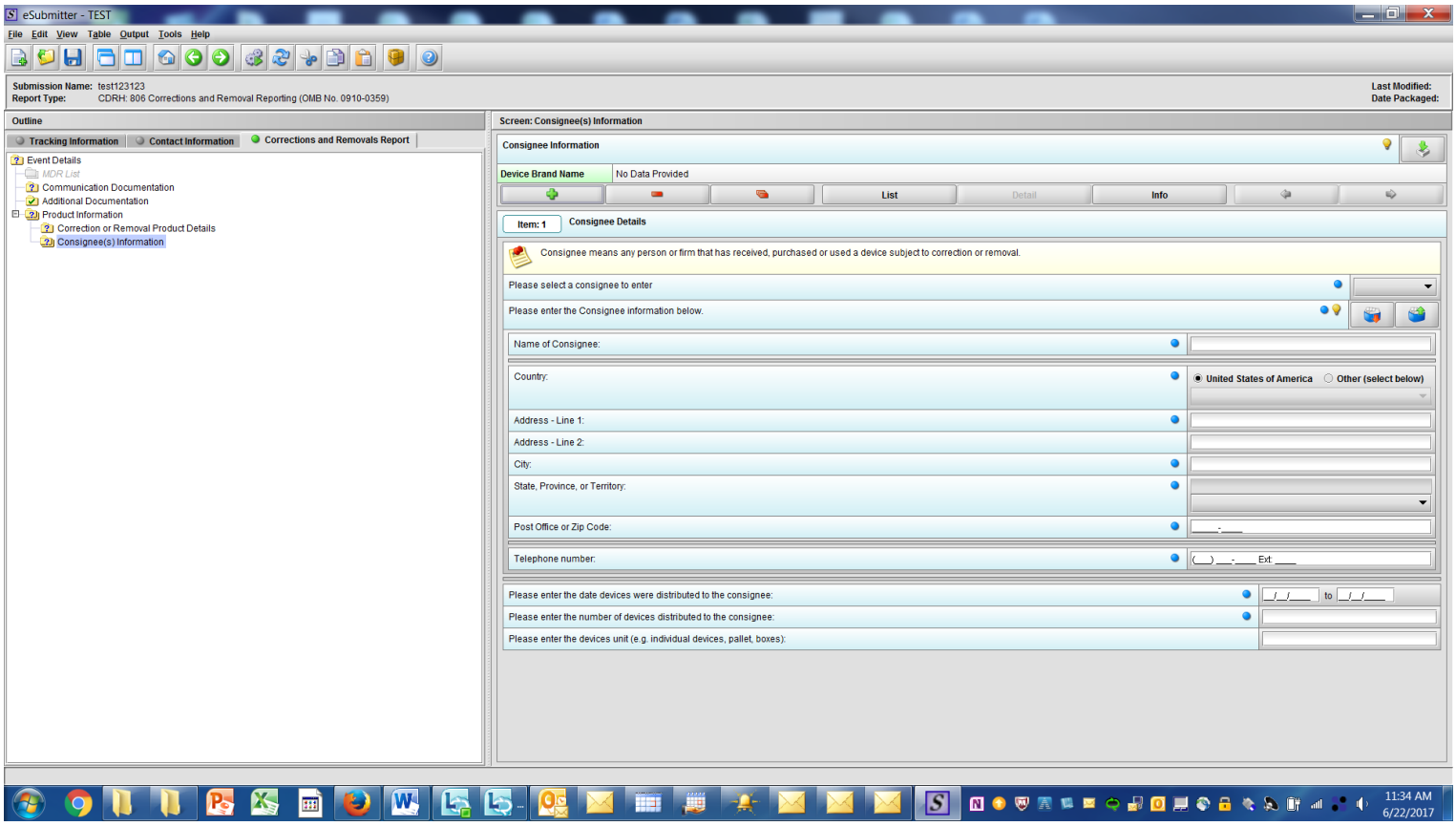
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
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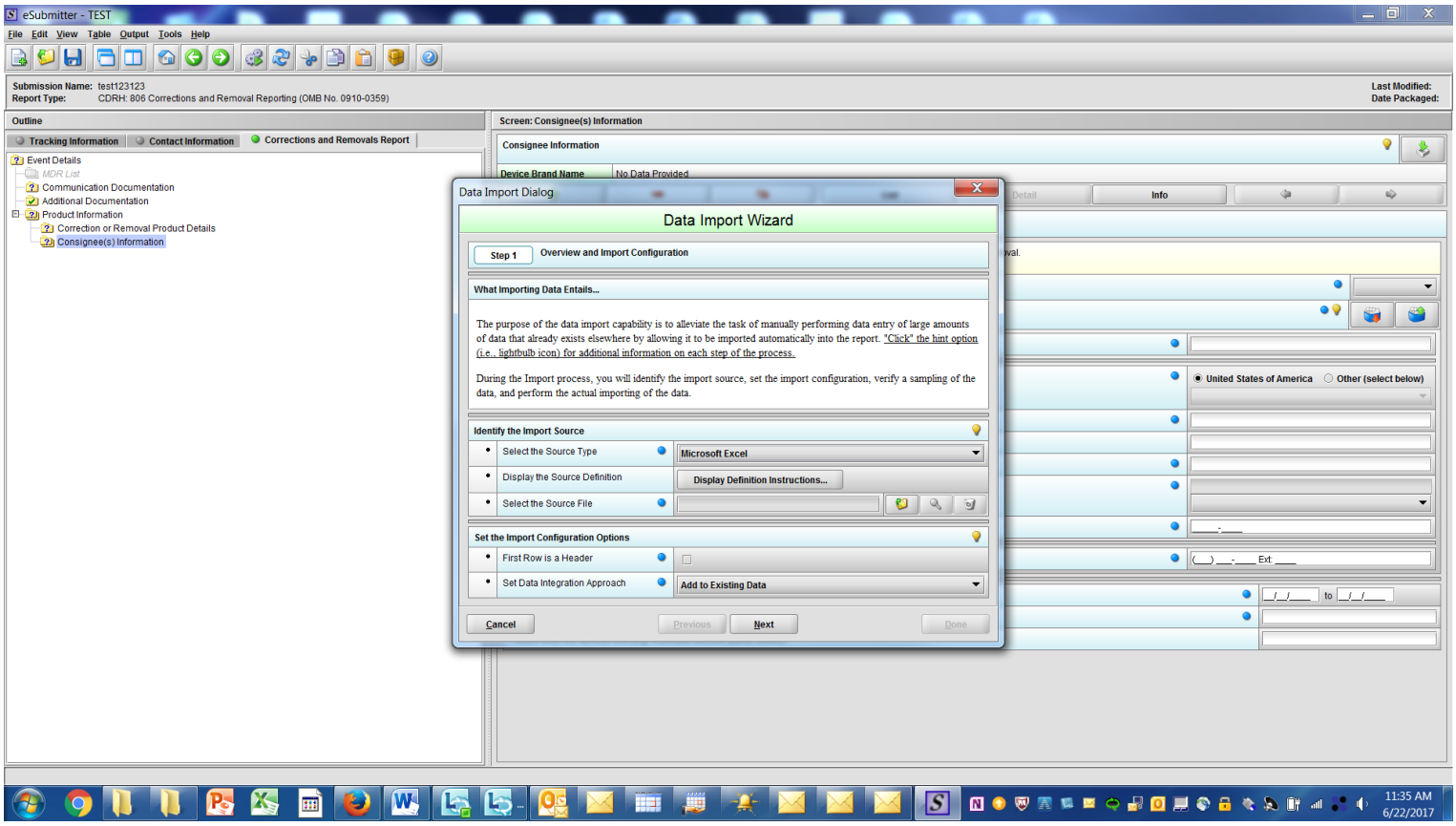
Event Details
MDR List
Communication Documentation
Additional Documentation
Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Consignee(s) Information
Consignee Information
Device Brand Name
No Data Provided
List
Detail
Info
Item: 1
Consignee Details
Consignee means any person or firm that has received, purchased or used a device subject to correction or removal.
Please select a consignee to enter
Please enter the Consignee information below.
Name of Consignee:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Telephone number:
Please enter the date devices were distributed to the consignee:
to
Please enter the number of devices distributed to the consignee:
Please enter the devices unit (e.g. individual devices, pallet, boxes):
11:34 AM
6/22/2017


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: test123123
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified:
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Product Information
Correction or Removal Product Details
Consignee(s) Information
Screen: Consignee(s) Information
Consignee Information
Device Brand Name
No Data Provided
Info
Data Import Dialog
Data Import Wizard
Step 1
Overview and Import Configuration
What Importing Data Entails...
The purpose of the data import capability is to alleviate the task of manually performing data entry of large amounts of data that already exists elsewhere by allowing it to be imported automatically into the report. "Click" the hint option (i.e., lightbulb icon) for additional information on each step of the process.
During the Import process, you will identify the import source, set the import configuration, verify a sampling of the data, and perform the actual importing of the data.
Identify the Import Source
Select the Source Type
Microsoft Excel
Display the Source Definition
Display Definition Instructions...
Select the Source File
Set the Import Configuration Options
First Row is a Header
Set Data Integration Approach
Add to Existing Data
Cancel
Previous
Next
Done
United States of America
Other (select below)
11:35 AM
6/22/2017