

eSubmitter - TEST

File Edit View Table Output Tools Help

Submission Name: zsd
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/cfr/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/cfr/rea.cfm>. For any additional questions regarding reporting requirements, please contact your FDA District Recall Coordinator (<http://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.

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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.

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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.

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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).

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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 Division 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

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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.):

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Manufacturer 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):

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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):

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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: () - Ext

Fax number: () -

Reference Numbers (for the Establishment Name specified above)

FDA Establishment Identifier (FEI):

Other Importer Information (e.g., website, etc):

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 - Event Details
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 - 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:

Code	Name
0 items in the list	

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:

Code	Name
0 items in the list	

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 - 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:

Code	Name
0 items in the list	

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:

Code	Name
0 items in the list	

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.):

Title	Name	Date	Size	Path
0 items in the list				

Please provide the MDR number(s) of the MDR(s) previously submitted to the FDA on next screen.

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 - Product Information
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 - 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

Title	Name	Date	Size	Path
-------	------	------	------	------

Please provide the MDR number(s) of the MDR(s) previously submitted to the FDA on next screen.

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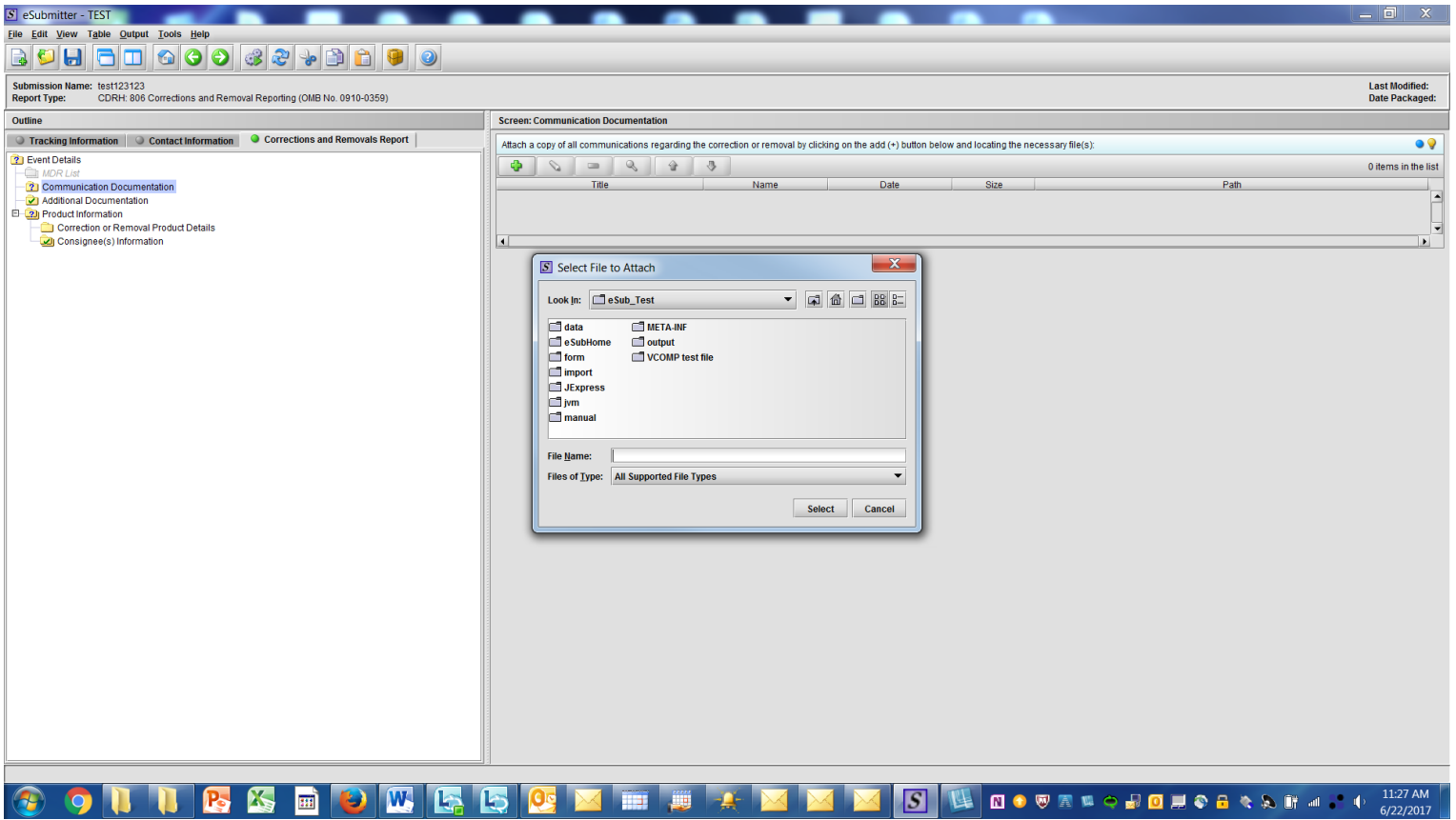
- Tracking Information
- Contact Information
- Corrections and Removals Report
 - Event Details
 - MCRI List
 - Communication Documentation
 - Additional Documentation
 - Product Information
 - Correction or Removal Product Details
 - Consignee(s) Information

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):

Title	Name	Date	Size	Path
0 items in the list				

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- Contact Information
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 - Event Details
 - MCR 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):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach any Root Cause Analyses by clicking on the add (+) button below and locating the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

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):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach any Health Hazard Assessments by clicking on the add (+) button below and locating the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach the Recall Strategy by clicking on the add (+) button below and locating the necessary files:

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach any additional relevant documents by clicking on the add (+) button below and locating the necessary file(s):

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Event Details

- MCRL 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):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach the Recall Strategy by clicking on the add (+) button below and locating the necessary files:

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Please attach any additional relevant documents by clicking on the add (+) button below and locating the necessary file(s):

Title	Name	Date	Size	Path
-------	------	------	------	------

Select File to Attach

Look In: eSub_Test

- data
- eSubHome
- form
- import
- JExpress
- jym
- manual
- META-INF
- output
- VCOMP test file

File Name:

Files of Type: All Supported File Types

Select Cancel

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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.

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 - Product Information
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Screen: Product Information

Product Information

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:

Product Code	Product Code Name	Device Class	Classification Panel	C.F.R. Section
0 items in the list				

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?

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Screen: Product Information

Product Information

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
- Premendment
- 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):

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Screen: Product Information

Product Information

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):

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Screen: Product Information

Product Information

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

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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:

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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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Screen: Consignee(s) Information

Consignee Information

Device Brand Name: No Data Provided

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: _____ Ext: _____

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): _____

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