CDRH Voluntary Compliance: Corrections and Removals Report

Tracking Information

Tracking Information

Please indicate which of the following actions you are reporting in this submission: •
( ) A new correction or removal report ( ) An expansion of an existing correction or removal ( ) Additional information for an existing correction or removal

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: •	( ) C ( ) R

Please identify the District Office to which this correction or removal applies: • Note: Select the FDA District Office in which the recalling firm is located. If you are a foreign manufacturer, select the FDA District Office in which the importer or US agent is located.

Contact Information

Submitter Information

Responsible Representative	
Please enter the following information about the Submitter below or select the information from the Address Book. •	
Contact Name	
Occupation Title	
Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
FEI	

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

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Manufacturer Information

Responsible Representative	
Please enter the following information about the Manufacturer below or select the information from the Address Book. •	
Contact Name	
Occupation Title	
Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
FEI	

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

Recalling Firm Information

Responsible Representative	
Please enter the following information about the Recalling Firm below or select the information from the Address Book. •	
Contact Name	
Occupation Title	
Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
FEI	

Other Recalling Firm Information (e.g., website, etc):

Importer Information

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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.

Contact Name	
Occupation Title	
Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
FEI	

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

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Event Details

Please select the regulatory violation being reported in this correction or removal:

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: [QUESTION TYPE NOT YET IMPLEMENTED: MDR CODE 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: [QUESTION TYPE NOT YET IMPLEMENTED: MDR CODE LIST]

Have you submitted MDR(s) to the FDA for any illnesses or injuries that have occurred with use of the device(s)?	( ) Yes ( ) No

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Please provide copies of MDR(s) previously submitted to the FDA (e.g. MedWatch Report 3500 or 3500A, complaint records, etc.):	
No Files Attached.	
Note:	Please provide the MDR number(s) of the MDR(s) previously submitted to the FDA on next 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): •
No Files Attached.

Additional Documentation

Additional Information
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):
No Files Attached.

Please attach any Root Cause Analyses by clicking on the add (+) button below and locating the necessary file(s):
No Files Attached.

Please attach any Corrective or Preventative Actions by clicking on the add (+) button below and locating the necessary file(s):
No Files Attached.

Please attach any Health Hazard Assessments by clicking on the add (+) button below and locating the necessary file(s):
No Files Attached.

Please attach the Recall Strategy by clicking on the add (+) button below and locating the necessary files:
No Files Attached.

Please attach any additional relevant documents by clicking on the add (+) button below and locating the necessary file(s):
No Files Attached.

Product Information

Device Brand Name: 1

Please enter the device brand name: •	
Please select the device common name by clicking on the add (+) button below and searching for the product code or name filter criteria: •	

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No product code selected.
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 enter the number:
No Information Provided.

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):	
No Information Provided.	
Please attach supporting documentation:	
No File Attached.	

Please indicate your method of providing the catalog number(s):	
Catalog Number(s):	
No Information Provided.	
Please attach supporting documentation:	
No File Attached.	

Please indicate your method of providing the serial number(s):	
Serial Number(s):	
No Information Provided.	
Please attach supporting documentation:	
No File Attached.	

Please indicate your method of providing the lot number(s):	
Lot Number(s):	

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No Information Provided.
Please attach supporting documentation:
No File Attached.

Please indicate your method of providing the other device identifier(s):	
Other Device Identifier(s):	
No Information Provided.	
Please attach supporting documentation:	
No File Attached.	

Correction or Removal Product Details

Please enter the total number of devices manufactured subject to the correction or removal: •		
>	Please enter the date range of manufacture:	

Please enter the total number of devices distributed subject to the correction or removal: •		
>	Please enter the date range of distribution:	

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:	

Consignee(s) Information