Please indicate which of the following actions you are reporting in this submission:

Tracking Information

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| 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: Please enter the Correction or Removal Report Type: 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 FDA District Office in which the importer or US agent is located. Contact Information Submitter Information Responsible Representative | 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 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: Please enter 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 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 | () Addition | pansion of an existing correction or removal | |
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| · | Establishment Name Division Name Address Telephone Number | Contact Submitter Responsible Please enter | Information Sele Representative er the following information about the Submitter below or select the information from the A | ddress Book. |
| Email Address | Division Name Address Telephone Number | Contact Submitter Responsible Please ente Contact Nar | Information Sele Representative er the following information about the Submitter below or select the information from the A | ddress Book. |
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| Taxitamos | | Contact Submitter Responsible Please enter Contact Nar Occupation Email Addres Establishme Division Nar Address | Information Ile Representative In the following information about the Submitter below or select the information from the Arme In title In title In the sess In the sess | ddress Book. |
| FEI | FEI | Contact Submitter Responsible Please enter Contact Narr Occupation Email Addres Establishmen Division Narr Address Telephone It | Information Ile Representative In the following information about the Submitter below or select the information from the Arme In title In title In the sess In the sess | ddress Book. |

Manufacturer Information

Responsible Representative

| Please enter the followi Book. | ng information about the Manufacturer below or select the information from the Address • |
|---|--|
| Contact Name | |
| Occupation Title | |
| Email Address | |
| Establishment Name | |
| Division Name | |
| Address | |
| Telephone Number | |
| Fax Number | |
| FEI | |
| Other Manufacturer Info | ormation (e.g., website, etc): mation |
| | |
| Responsible Represer | ntative |
| | ing information about the Recalling Firm below or select the information from the Address • |
| Please enter the followi | |
| Please enter the followi Book. | |
| Please enter the followi Book. Contact Name | |
| Please enter the following Book. Contact Name Occupation Title | |
| Please enter the following Book. Contact Name Occupation Title Email Address | |
| Please enter the following Book. Contact Name Occupation Title Email Address Establishment Name | |
| Please enter the following Book. Contact Name Occupation Title Email Address Establishment Name Division Name | |
| Please enter the following Book. Contact Name Occupation Title Email Address Establishment Name Division Name Address | |
| Please enter the following Book. Contact Name Occupation Title Email Address Establishment Name Division Name Address Telephone Number | |
| Please enter the followi Book. Contact Name Occupation Title Email Address Establishment Name Division Name Address Telephone Number Fax Number FEI | |

Importer Information

| Is there an importer? | | () Yes () No | | | |
|---|---|-------------------|--|--|--|
| Responsible Represe | ntative | | | | |
| Please enter the followi | ng information about the Importer below or select the information from the Addre | ess Book. | | | |
| Contact Name | | | | | |
| Occupation Title | | | | | |
| Email Address | | | | | |
| Establishment Name | | | | | |
| Division Name | | | | | |
| Address | | | | | |
| Telephone Number | | | | | |
| Fax Number | | | | | |
| FEI | | | | | |
| Other Importer Information | tion (e.g., website, etc): | | | | |
| | | | | | |
| Corrections and Event Details | Removals Report | | | | |
| 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 ME device(s)? | DR(s) to the FDA for any illnesses or injuries that have occurred with use of the | () Yes () No | | | |

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:

| 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) Pren Notification () Premarket () Exempt () Preamendn () Other | Approval (PMA) |
| 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 | |
| Please indicate your method of providing the device model number(s): | | | | |
| Device Model Number(s): | | | | 1 |
| 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. | | | | |
| Diagon indicate your method of providing the let awar average | | | | |
| Please indicate your method of providing the lot number(s): Lot Number(s): | | | | |

CDRH Voluntary Compliance: Corrections and Removals Report 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:

Consignee(s) Information

life date:

Please describe the device expiration date or expected end of