Allegation Report

Allegation Report

Tracking Information

Have you previously submitted this allegation to the FDA?	( ) Yes ( ) No

If known, please enter the FDA assigned allegation number (CPT or COM number):	
Please indicate why you are contacting the FDA regarding the previous allegation:	
( ) To provide additional information regarding the allegation (e.g. corrective action plan, etc.). ( ) To check on the status of the allegation. ( ) Other	
> If Other, please indicate why you are contacting the FDA regarding the previous allegation:	
Please identify the subject matter or type of complaint you are reporting to the FDA:	
> If Other, please specify further:	

Please select your relationship to the product and/or manufacturer of the product reported in this allegation: •	
> If Other, please specify relationship:	

Allegation Narrative Information

Please describe in as much detail as possible the event(s), injuries and/or illnesses bringing about this allegation (Max 4000 Characters): •
Please provide any additional information you feel will assist the FDA in addressing this allegation. Attach documents by clicking on the add (+) button below and locating the necessary files on your computer:
No Files Attached.

Please select the most appropriate patient problem codes associated with your allegation 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]

Please select the most appropriate device problem codes associated with your allegation 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]

Reporter Information

Please indicate whether you would like your personal identification information to remain confidential. Note: All •	

personal identifiers will be protected in accordance with the Freedom of Information Act (FOIA), Privacy Act and 21 Code of Federal Regulations (CRF) Parts 20 and 21	

Please enter your contact information below.	
Contact Name	
Email Address	
Address	
Telephone Number	

If CDRH needs to contact you (e.g., follow up questions, etc), please indicate your preferred method of communication:		
>	If Other, please specify the preferred method of communication:	

Manufacturer Information

Please enter the Manufacturer information below as much as possible.	
Contact Name	
Email Address	
Manufacturer Name	
Address	
Telephone Number	
Fax Number	
FEI	

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

Importer Information

Please enter the Importer information below as much as possible.	
Contact Name	
Email Address	
Importer Name	
Address	
Telephone Number	

Allegation Report

Fax Number	
FEI	

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

Product Information

Is your allegation referencing an individual product (single unit) or all products of this type?	( ) All Types ( ) Single Unit ( ) Unknown

Please enter the brand and/or proprietary name of the product:	
Please select the product common name by clicking on the add (+) button below and searching for the product code:	
No product code selected.	
Enter the Unique Device Identifier (UDI), if known:	

Please indicate all of the product identifiers you will be submitting:	[ ] Device Model Number [ ] Catalog Number [ ] Serial Number [ ] Lot Number [ ] Other Identification Number

Please indicate your method of providing the model number(s):	
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:	

Allegation Report

No File Attached.

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

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

Please select the appropriate marketing status of the product:	( ) 510(k) Premarket Notification ( ) Premarket Approval (PMA) ( ) Exempt ( ) Preamendment ( ) Unknown ( ) Other
Please provide the number, if known.	
No Information Provided.	
Please enter the age of the product:	
> Please specify the units for the age of the product:	( ) Day(s) ( ) Month(s) ( ) Year(s)
Please enter the expiration date of the product, if known (MM/DD/YYYY):	

Please describe the intended use of the product:

Purchasing Information

What was the product status at the date of purchasing or acquiring the product?		
>	If Other, please specify the product status at the date of purchasing or acquiring the product:	

Please enter the location where the product was purchased below.	
Purchasing Location Name (e.g.	

Allegation Report

Pharmacy, Department Store, etc.)	
Address	
Telephone Number	
Fax Number	

Other Purchasing Location Information (e.g., website, etc):

Medical Device Reporting

Have you submitted related information in the form of a Medical Device Report (MDR) to the FDA?	( ) Yes ( ) No
Please enter MDR number(s) by clicking the add (+) button below, if known:	
No Information Provided.	
If applicable, please provide copies of MDR(s) previously submitted to the FDA (e.g., MedWatch Report 3500 or 3500A, complaint records, etc.):	
No Files Attached.	