OMB Control Number: 0910-0359
Expiration Date: 10/31/2023

Device Correction/Removal Report for Industry

Paperwork Reduction Act Disclosure Notice

[Form Instructions]

To facilitate your recall, we have included the link to our "Recalls, Market Withdrawals & Safety Alerts" web page. This link is intended to provide guidance and instruction to FDA regulated industry regarding product recalls: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.

21 CFR Part 806 requires manufacturers and importers to notify FDA of certain device corrections and removals actions. We recommend these be reported to your Division Recall Coordinator electronically. Please also submit the draft letter and recall strategy prior to initiation. It is recommended to not wait until all information is completed, but to submit this information as soon as possible. This "early" notification will allow FDA the opportunity to review and comment on your written notification and to offer guidance and assistance in your recall process.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=806.10

FDA DEVICE RECALL CONTACTS:

When recalling firm (initiating recall) is in: CT, DE, IN, KY, MA, ME, MD, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV and the District of Columbia.
oradevices1recalls@fda.hhs.gov

When recalling firm (initiating recall) is in: AL, FL, GA, IA, IL, KS, LA, MN, MO, MS, NC, ND, NE, SC, SD, TN, WI, Puerto Rico, and the US Virgin Islands.
oradevices2recalls@fda.hhs.gov

When recalling firm (initiating recall) is in: AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA and WY.
oradevices3recalls@fda.hhs.gov

Firm Information

Recalling Firm

FDA Establishment Identifier (FEI) | Firm Type

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

Comments

If your product is imported into the US please provide the following info below FEI, establishment name, and address.

Importer Information

Top Firm Official / Most Responsible Individual

Official's Name | Title

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Manufacturer

FDA Establishment Identifier (FEI)

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Firm Information Cont'd

Additional Manufacturer, if applicable

FDA Establishment Identifier (FEI)

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Recall Contact at Recalling Firm

Official's Name | Title

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Additional Recall Contact at Recalling Firm, if applicable

Official's Name | Title

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Firm Information Cont'd

Public Contact

Official's Name | Title

Firm Name

Address

City | State/Province | Postal Code | Country

Telephone ***No Dashes*** *(Add International Phone Number to Comments)* | Area Code | Number | Ext | Country Code

E-mail Address

Comments

Event Information

Identify Reason for Recall

Firm Awareness Date | Recall Initiation Date

Please enter the Minimum and Maximum Manufactured and Distribution Dates below.

Manufactured Dates From To ☐ Check if product is still being manufactured.

Distribution Dates From To ☐ Check if product is still being distributed.

How was the problem discovered? If discovery was through testing, please provide copies of the analysis.

Any reported illness or injury? ○ Yes ○ No

If yes, describe the types of injuries and provide MDR number.

Did you conduct a Health Hazard Evaluation (HHE)? If so, please include a copy. ○ Yes ○ No

Event Information Cont'd

Provide details if you have determined a root cause for the problem.

Number of complaints received (provide copies)

MDR Submitted? (provide copies) ○ Yes ○ No

If so, how many: Deaths? Injuries? Malfunctions? Other?

Report of Corrections and Removal number ([Registration # or FEI]/mmddyyyy/RorC/#####)

What criteria did you use to establish the scope of the recall?

Distribution Details

Please provide a complete listing of all locations where this product was sent to.

- Please include the following information in Microsoft Excel (each in its own cell): Customer name/ physical address/ city/ state / zip code /telephone (please avoid duplicate consignee locations)
  - Please separate foreign and domestic consignees
  - Please separate Military and Government consignees

Please fill in the box below as to the number of Government consignees. If no Government consignees indicate None.

Government/ DoD Addresses / Comments

Please fill in the box below with the Distribution Pattern, such as states and countries the product was distributed too.

Distribution Details

# of Domestic Consignees # of Foreign Consignees

Please fill in the table below as to the number of each type of consignee, for U.S. only, including Government consignees.

Consignees	Approx. Number
Distributor	
Retailer	
Institution	
Medical Facility	
Internet Sales	

Consignees	Approx. Number
Physician	
Consumer/Patient	
Re-packer / Relabeler	
Direct Accounts	
Veterans Administration	

Consignees	Approx. Number
Department of Defense	
Manufacturer	
USDA	
Other	

Event Information Cont'd

Recall Strategy

Indicate the customer level to which you are extending the recall.(i.e. wholesale, hospital, retail, consumer, etc.)

If your recall only extends to the wholesale/distributor level, please justify.

Indicate the method of notification (i.e. mail, phone, facsimile, e-mail, letter, visit).

Indicate the date the notification was was first issued. It is advisable to include a written notification, so customer will have a record of the recall and your instructions.

If letters will be sent, indicate how letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile), and whether a third-party recall company is being used (provide name and address of third party)

Indicate the date you notified specific consignees, if different from the notification date.

Instructions:

- If initial notification is by phone, you must provide a copy of the phone script to FDA and the date(s) that notification was attempted and/or achieved.
- If you have a web site, you should consider posting the recall notifications on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)
- Please attach a copy of your customer notification.

Report on what you have instructed customers to do with the recalled product.

How are you determining if the recall is effective? What effectiveness checks are you conducting?

NOTE: Effectiveness checks are your means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then you should take necessary steps to make the recall effective. These steps may involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

How are you planning on following up with customers who do not respond?

Determine and provide your course of action for out-of-business distributors.

If the product is to be "reconditioned" or corrected, provide details of the reconditioning or correction plan and seek concurrence by your FDA Recall Coordinator prior to implementation.

Event Information Cont'd

What are you planning to do with any returned product?

How are you going to store it?

What is the destruction plan? Provide the details (date, method, and location) prior to destruction in the event FDA would like to witness the action.

What preventative measures have you taken or are planning to take to prevent this event from occurring again? Please provide a copy of the final CAPA

Press Releases

- In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate.
- If a press release was issued or will be issued, please submit a copy.
- Issuance of a press release should be the highest priority and it should be issued promptly.
- Unique situations will be handled on a case-by-case basis.

*You should consult with your respective Recall Coordinator before issuance of a press release whenever possible.
*Submit press release to an appropriate newswire that will reach all intended consumers.
**For example: The AP- send the press release in the body of an email (no attachments) to info@ap.org
NOTE: For those recalls where FDA believes a Press Release is warranted, the Agency may issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.

If not issuing press release, please submit justification.

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format) as well as product inserts and any information sheets for all products being recalled.

Product 1 (additional products can be entered at the end of this document) Product Code Builder

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. *Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.*

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No | Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No | Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 2

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. *Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.*

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 3

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 4

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 5

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

F*or Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.*

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 6

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ◯ Yes ◯ No

Is this a tracked device? ◯ Yes ◯ No

Is product controlled by software? ◯ Yes ◯ No

Is this an implantable device? ◯ Yes ◯ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

-

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 7

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 8

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 9

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 10

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 11

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 12

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 13

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 14

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 15

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 16

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 17

Industry Code

Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life

Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 18

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ○ Yes ○ No

Is this a tracked device? ○ Yes ○ No

Is product controlled by software? ○ Yes ○ No

Is this an implantable device? ○ Yes ○ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 19

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ◯ Yes ◯ No

Is this a tracked device? ◯ Yes ◯ No

Is product controlled by software? ◯ Yes ◯ No

Is this an implantable device? ◯ Yes ◯ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined

Product Information

Include a complete copy of all labeling (preferably in color and .jpeg format). Include product inserts and any information sheets for all products being recalled.

Product 20

Industry Code | Product Code

Brand Name

Product Name

Model/ Catalog Number

Software version, if applicable

For Product Description please include common name and/or general use category (ie. Cardiac catheter, urinary catheter), volume, packaging, etc.

Product Description

Is it a component? If so, what is it a component of?

For Product Identifying Codes please include all applicable elements: UDI, GTIN, Lot Numbers, Serial Numbers, Software Revisions, Expiration Date. Whatever distinguishes the recalled product from product that is good. If you say, "all lots," differentiate the recalled product from future production (all lots up to ### or date). Please format in the following manner: Model No XXXXX; UDI-DI XXXXXXXX; Lot Numbers/Serial Numbers 0000000, 1111111, etc.

Product Identifying Code(s)

Expected Life | Shelf Life

Indication of Use

510K/PMA Number

Is product sterile? ◯ Yes ◯ No

Is this a tracked device? ◯ Yes ◯ No

Is product controlled by software? ◯ Yes ◯ No

Is this an implantable device? ◯ Yes ◯ No

Total Quantity Manufactured (eaches only)

Manufactured Dates From To ☐ Check if product is still being manufactured.

Product Quantity Distributed (eaches only)

Distribution Dates From To ☐ Check if product is still being distributed.

Amount of Product Quarantined