FDA

See Related Information[22]

Class 2 Device Recall BARD MYPICC Kit, REF CK000095B

Date Initiated by Firm	January 12, 2018
Create Date	July 06, 2018
Recall Status[1]	Completed
Recall Number	Z-2378-2018
Recall Event ID	80197[23]
Product Classification	Central venous catheter tray[24] - **Product Code** OFF[25]
Product	BARD MYPICC Kit, REF CK000095B, 5F French Size, packaged 5 kits/case, Sterile, RX, For use in vascular access procedures.
Code Information	Lot 17YM5936, Exp. 04/30/2019
Recalling Firm/ Manufacturer	Medline Industries, Inc. 1170 S Northpoint Blvd Waukegan IL 60085-6757
For Additional Information Contact	Kassandra Cotner 866-359-1704
Manufacturer Reason for Recall	One of the cases of product might not have been sterilized.
FDA Determined Cause [2]	Process control
Action	The recalling firm's sales representative telephoned their one customer on 1/12/2018 requesting return of the product.
Quantity in Commerce	6/5-kit cases
Distribution	The product was distributed to UT.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm