Class 2 Device Recall Terumo Cardiovascular Systems

See Related Information [22]

Date Initiated by Firm	December 20, 2018
Create Date	February 27, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0966-2019
Recall Event ID	82019[23]
Product Classification	Cardiovascular procedure kit[24] - **Product Code** OEZ[25]
Product	Cardiovascular Procedure Kit (CLR MP4 COIL 2 SPIKE) Catalog Number: 140222
Code Information	Lot Numbers: V A30
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 125 Blue Ball Rd Elkton MD 21921-5315
Manufacturer Reason for Recall	Presence of natural rubber latex is not declared in the label
FDA Determined Cause [2]	Component design/selection
Action	Terumo issued Urgent Medical Device Recall dated 12/20/18 stating reason for recall, health risk and an appropriate course of action for the return of affected product to Terumo. Questions or concerns: Terumo CVS Customer Service: 1.800.521.2818 Monday ¿¿ Friday, 8 a.m. ¿¿ 6 p.m. ET.
Quantity in Commerce	12 packs
Distribution	TX
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.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.