Class 2 Device Recall Custom Made Tracheostomy Device

Date Initiated by Firm: July 15, 2016
Create Date: February 09, 2018
Recall Status: Open, Classified
Recall Number: Z-0577-2016
Recall Event ID: 79045
Product Classification: Tube tracheostomy and tube cuff. Product Code JOH
Product: Custom Made Tracheostomy Device

The CADD Administration Sets with Flow Stop are designed to be used with a variety of CADD ambulatory infusion pumps to allow fluid delivery from an IV bag.

Code Information: GS025081
Recalling Firm/Manufacturer: Smiths Medical ASD, Inc.
5700 W 23rd Ave
Gary IN 46406-2617
For Additional Information Contact: 219-989-9150
Manufacturer Reason for Recall: Smiths Medical determined that a single custom Tracheostomy device had been shipped to the customer without required sterilization.
FDA Determined Cause: Under Investigation by firm
Action: The firm, Smith Medical, notified the consignee by phone on July 29, 2017 of the Field Corrective Action Report. The consignee was instructed to return the devices for destruction and replacement. If you have any questions, contact VP, Global Quality and Regulatory at 219-989-9150.
Quantity in Commerce: 1
Distribution: International Distribution to Germany
Total Product Life Cycle: TPLC Device Report

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.
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.

Links on this page:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161230 2/19/2018