Date Initiated by Firm: April 25, 2017
Create Date: June 14, 2017
Recall Status: Open, Classified
Recall Number: Z-2537-2017
Recall Event ID: 77217
Product Classification: Laparoscopic accessories, gynecologic - Product Code NWY
Product: Clarke-Reich Laparoscopic Knot Pusher
Code Information: All lots, Catalog numbers: J-CRKP-042900
Recalling Firm/Manufacturer: Cook Inc.
750 N Daniels Way
Bloomington IN 47404-9120
For Additional Information Contact: Cook Medical Customer Relations Department
800-457-4500
Manufacturer Reason for Recall: reprocessing instructions do not provide sufficient detailed information for the cleaning, disinfection, and sterilization of these products
FDA Determined Cause: Labeling design
Action: On 4/25/2017, URGENT: MEDICAL DEVICE RECALL notifications were sent to the affected consignees via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification.
Quantity in Commerce: 178
Distribution: The devices have been distributed nationwide within the United States and the following countries: Australia, Belgium, Canada, Finland, Germany, Guatemala, Hong Kong, India, Ireland, Japan, South Korea, Kuwait, Malaysia, Netherlands, New Zealand, Puerto Rico, Saudi Arabia, Taiwan, and the United Kingdom.
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=155462

6/19/2017