FDA

Class 2 Device Recall ClarkeReich Laparoscopic Knot Pusher

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See Related Information[22]

Date Initiated by Firm	April 25, 2017
Create Date	June 14, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2537-2017
Recall Event ID	77217[23]
Product Classification	Laparoscopic accessories, gynecologic[24] - **Product Code** NWV[25]
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 Departme 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 [2]	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[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.

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