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Class 2 Device Recall Ally Uterine Positioning System (Ally UPS)

Class 2 Recall
Ally Uterine Positioning System (Ally UPS)

Date Posted: June 08, 2015
Recall Status: Open
Recall Number: Z-1727-2015
Recall Event ID: 7130624
Premarket Notification 510(K) Number: K141523

Product Classification: Cannula, Manipulator/Injector, Uterine - Product Code: LKF

Product: Ally Uterine Positioning System (Ally UPS) used in the mounting and positioning and holding of uterine manipulators during gynecological laparoscopic procedures
Model: Ally UPS

Code Information: Serial Numbers: 020015, 020021, 020023, 020043, 020051

Recalling Firm/Manufacturer: CooperSurgical, Inc.
75 Corporate Dr
Trumbull, Connecticut 06611-1350

For Additional Information Contact: Nana Banao
203-601-5200 Ext. 3350

Manufacturer Reason for Recall: Design of device may expose user to injury to fingers or body parts

FDA Determined Cause: DESIGN: Device Design

Action: CooperSurgical initiated the recall on May 18, 2015 via FedEx with confirmed delivery receipt. The letter identified the affected product and asked users to discontinue use and complete the Acknowledgement and Receipt Form to schedule a replacement. Questions contact 203.601.5200.

Quantity in Commerce: 5 units

Distribution: Distributed in the states of CA, IL, NC, and NY.

Total Product Life Cycle: TPLC Device Report

1. For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 67.55
2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = LKF and Original Applicant = COOPER SURGICAL, INC.

Links on this page:

6/24/2015