Class 2 Recall
Ally Uterine Positioning System
(Ally UPS)

See Related Information[23]

Date Posted	June 08, 2015
Recall Status[1]	Open
Recall Number	Z-1727-2015
Recall Event ID	71308[24]
Premarket Notification 510(K) Number	K141523[25]
Product Classification	Cannula, Manipulator/Injector, Uterine[26] - **Product Code** LKF[27]
Product	Ally Uterine Positioning System (Ally UPS) used in the mounting and positioning and holding of uterine manipulators during gynecological laproscopic 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 Banafo 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 [2]	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[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[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.[30]

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