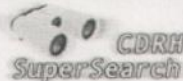


FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall CooperSurgical

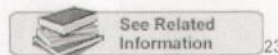


6 510(k) | DeNovo⁹ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | HDE¹³ | Classification¹⁴ | Standards¹⁵
 7 | CFR Title | Radiation-Emitting Products¹⁷ | X-Ray Assembler¹⁸ | Medsun Reports¹⁹ | CLIA²⁰ | TPLC²¹ | Inspections²²
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Class 2 Recall CooperSurgical



Date Posted	July 17, 2015
Recall Status¹	Open
Recall Number	Z-2098-2015
Recall Event ID	71582²⁴
Product Classification	Dilator, Vaginal²⁵ - Product Code HDX²⁶
Product	Milex Vaginal-Hymenal Silicone Dilators Set of 4 P/N MX20 Product Usage: The CooperSurgical Milex Vaginal-Hymenal Silicone Dilators are used for progressive vaginal dilation therapy involving the treatment of vaginismus (muscular spasm of the vagina) and conditions that result in constriction of the vaginal and/or rectal orifice
Code Information	LOT 156966
Recalling Firm/Manufacturer	CooperSurgical, Inc. 75 Corporate Dr Trumbull, Connecticut 06611-1350
For Additional Information Contact	SAME 203-601-5200
Manufacturer Reason for Recall	Incorrect expiration date on outer carton kit label
FDA Determined Cause²	EXPIRATION DATING: Incorrect or No Expiration Date
Action	CooperSurgical sent an Urgent Medical Device Recall dated June 19, 2015 to affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to discontinue use of the affected products and complete the attached Acknowledgement and Receipt Form for a replacement. For questions call 203.601.5200.
Quantity in Commerce	40 kits
Distribution	US Nationwide Distribution in the states of: CA, FL, GA, HI, IL, KY, MD, MN, NC, NY, OH, TX, VT, and WA.
Total Product Life Cycle	TPLC Device Report²⁷

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁸](#)

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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