Class 2 Device Recall Medline EZ Lubricating Jelly

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Date Initiated by Firm	December 12, 2016
Create Date	January 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0984-2017
Recall Event ID	75948[23]
510(K)Number	K041060[24]
Product Classification	Lubricant, patient[25] - **Product Code** KMJ[26]
Product	Medline E-Z Lubricating Jelly; Bacteriostatic. Water Soluble. Sterile. 2 FL OZ (59 ml). Product Usage: For medical purposes to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices. Single use only. Sterile if unopened, undamaged package.
Code Information	Lot Numbers: 6I26; Unit No: MDS032285; Expiration Date: 08/2019
Recalling Firm/ Manufacturer	MEDLINE IND 3 Lakes Dr Northfield IL 60093-2753
Manufacturer Reason for Recall	Product was not sterilized. Product was shipped to distribution centers instead of the sterilization facility due to an operations error by a 3rd party shipping company.
FDA Determined Cause [2]	Process control
Action	Medline Industries sent a recall notification letters dated December 12, 2016 to customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to quarantine any affected product on hand and return product to Medline Industries for credit. Distributors were instructed to notify their customers and have them return affected product as well. For questions contact 866-359-1704.
Quantity in Commerce	12,024 tubes
Distribution	Worldwide Distribution - US Nationwide in the states of AL, FL, GA, IA, IL, IN LA, MI, PA, TX, WI, and the country of Canada
Total Product Life Cycle	TPLC Device Report[27]

[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[28].

[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.