Class 2 Device Recall OERPro Endoscope Reprocessor

Date Initiated by Firm	June 23, 2016
Create Date	October 19, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0138-2017
Recall Event ID	74542[23]
510(K)Number	K103264[24]
Product Classification	Accessories, cleaning, for endoscope[25] - **Product Code** FEB[26]
Product	OER-Pro Endoscope Reprocessor, Endoscope washer/disinfector
Code Information	Model: OER-Pro, All serial numbers affected
Recalling Firm/ Manufacturer	Olympus Corporation of the Americas 3500 Corporate Pkwy PO Box 610 Center Valley PA 18034-0610
For Additional Information Contact	Laura Storms 484-896-5688
Manufacturer Reason for Recall	New warning requiring Users to conduct duodenoscope precleaning and manual cleaning even when using an Automated Endoscope Reprocessor (AEI may indicate a user could forego certain steps in precleaning and manual cleaning of the endoscopes.
FDA Determined Cause [2]	Under Investigation by firm
Action	Olympus America Inc. (OAI) mailed a letter to customers informing them that they are issuing an updated Operation Manual for the OER-Pro Automated following actions were asked to be taken: -Olympus has discontinued previously distributed copies of the OER-Pro Operation Manual. - Inspect your inve and discard any existing inventory of OER-Pro Operation Manuals. - Implement use of the enclosed OER-Pro Operation Manual, which contains the nev 80. - Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the requirement to perform precleaning and manual cle duodenoscopes prior to placing the duodenoscopes in the OER-Pro for high level disinfection. - Additional copies of the new OER-Pro Operation Manua contacting our Technical Assistance Center at 1-800-848-9024, option 1, or by indicating on the enclosed questionnaire. Additional Operation Manuals w Please indicate on the enclosed questionnaire that you have received this notification. Fax the completed form to (484) 896-7128.
Quantity in Commerce	2, 686 units
Distribution	Distributed to: AK,AL,AR,AZ,CA,CO,CT,DC,DE,FL,GA,HI,IA,ID,IL,IN,KS,KY,LA,MA,MD,ME,MI,MN,MO,MS,MT,NC,ND,NE,NH,NJ,NM,NV,NY,OH,OK,OR,PA,RI,SC,TN
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, a 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.

510(K) Database 510(K)s with Product Code = FEB and Original Applicant = OLYMPUS MEDICAL SYSTEMS CORPORATION[29]

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