Class 2 Device Recall Ureteroreno videoscope URFV2 and URFV2R

See Related Information[22]

Date Initiated by Firm	December 12, 2016
Create Date	February 24, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1252-2017
Recall Event ID	75993[23]
510(K)Number	K072957[24]
Product Classification	Endoscope, accessories, narrow band spectrum[25] - **Product Code** NWB[26]
Product	Uretero-reno videoscope URF-V2 and URF-V2R endoscope and accessories The URF-V2/V2R endoscopes are intended for use in endoscopic diagnosis and treatment within the ureter and kidney.
Code Information	All serial numbers
Recalling Firm/ Manufacturer	Olympus Corporation of the Americas 3500 Corporate Pkwy PO Box 610 Center Valley PA 18034-0610
Manufacturer Reason for Recall	Olympus has received complaints regarding the breakage of the endoscope's insertion tube bending section during surgical procedures. Some of these complaints are associated with tissue trauma, including perforation, and insertion tubes which were stuck inside the patient and had to be surgically removed.
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm, Olympus, sent an "Urgent Medical Device Safety Notice" on December 29, 2016, to those that were affected by this issue. The letter addressed the corrective actions Olympus were taking to address the issue. Consignees were asked to inspect their inventory for the specified device, review the enclosed Instructions for Safe Use, which provided instructions to assist with understanding the Warnings and Cautions and complete and return the OLYMPUS URGENT MEDICAL DEVICE SAFETY NOTIFICATION via fax to: Olympus Regulatory Affairs Department at 484-896-7128.
Quantity in Commerce	1,627 units (769 URF-V2 and 858 URF-V2R)
Distribution	Worldwide distribution-US Nationwide and 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