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Class 2 Device Recall Pentax Video Duodenoscope

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Class 2 Device Recall Pentax Video Duodenoscope



Date Initiated by Firm January 17, 2017

Create Date July 11, 2017

Recall Status¹ Open³, Classified

Recall Number Z-2713-2017

Recall Event ID 77308²³

510(K)Number K092710²⁴ K963056²⁵

Product Classification duodenoscope and accessories, flexible/rigid²⁶ - **Product Code** FDT²⁷

Product Video Duodenoscope

These instruments are intended to provide optical visualization of (via a video monitor), and therapeutic access to, the biliary tract via the upper GI tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: esophagus, stomach, duodenum, common bile, hepatic and cystic ducts.

Code Information Model Numbers: Ed-3490TK and ED-3270K

Recalling Firm/Manufacturer Pentax of America Inc
3 Paragon Dr
Montvale NJ 07645-1782

For Additional Information Contact Mr. Paul Silva
800-431-5880 Ext. 2064

Manufacturer Reason for Recall Pentax initiated a field correction/safety alert for two (2) models of the Video Duodenoscope to determine how soiling may have occurred on the surface of the suction cylinder and under the distal cap during testing.

FDA Determined Cause² Device Design

Action The firm, Pentax Medical, sent a "FIELD CORRECTION" letter dated January 17, 2017 to their affected customers via USPS Certified Mail. The letter described the product, problem and actions to be taken. The customers were instructed to immediately remove any affected product from use; follow product labeling; ensure all reprocessing personnel are knowledgeable and thoroughly trained on the instructions of Use for manual reprocessing of the devices; clean elevator recesses and follow all reprocessing instructions; and complete and return the FIELD CORRECTION RESPONSE FORM via a member of the PENTAX Service Department as part of an on-site-visit or Fax to: QA/RA Department at 201-799-4063 (alternate 201-391-4189) or a pdf copy to customeradvisories@pentaxmedical.com. The firm will replace any affected product with its current generation model. If you have questions or request further information or assistance contact PENTAX Medical Customer Support at 1-800-431-5880 (8:30AM - 5:00PM, Monday-Friday, EST) or email: customeradvisories@pentaxmedical.com.

Quantity in Commerce 2,015 (US - 519 (ED-3490TK) and 5 (ED-3270K); OUS - 1,491)

Distribution Worldwide Distribution-US (Nationwide) including states of: AL, AZ, CA, CO, CT, DC, DE,