FDA

Class 2 Device Recall Pentax Video Duodenoscope

See Related Information[22]

Date Initiated by Firm	February 13, 2018
Create Date	February 20, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0643-2018
Recall Event ID	79237[23]
510(K)Number	K161222[24] K092710[25]
Product Classification	Duodenoscope and accessories, flexible/rigid[26] - **Product Code** FDT[27]
Product	Pentax Video Duodenoscope Model: ED-3490TK (UDI of design being recalled: 04961333232420) 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	A110122 A110140 H111024 , A110159 A110163 A110165 A110167 A110168 A110170 H110864 H110879 H110884 H110885 H110886 H110965 H111169 , A110347 H110790 , H110960 , A110243 A110246 , A110157 , A110527 A110534 , A110208 , A110589 H110909 H110983 , H110899 H110976 , A110306 A110307 A110491 A110495 , A110492 A110496 A110497 A110498 A110352 A110405 , H111012 H111019 , A110518 H110967 , A110649 A110667 H110803 , H110723 H110736 H110737 H110738 , A110316 H110969 , A110128 , A110036 A110038 , A110304 A110305 , A110422 A110424 , H110754 H111036 , H111042 , A110549 A110550 A110555 H110710 H110717 H110721 H110733 H110923 , H110893 , H110827 H110840 , H110961 H110990 , A110308 , A110083 , H111015 H111023 , H110958 H110968 , A110080 A110438 , H110860 , A110671 A110674 A110677 , H110749 , H110863 H110987 H111011 , A110077 A110338 , A110209 A110211 A110244 , A110079 A110082 , H110910 H110984 , A110134 , H110799 H110800 , H111066 , A110230 H110795 H110796 , H110890 H110894 , H110954 H110999 , H110914 H110953 H110959 H110962 , H110862 H110866 , H110897 H110955 , A110285 H110835 H110956 H110979 , A110610 , H110966 H110982 H111004 , H110906 H110912 H110957 , H110788 , A110274 A110275 H110920 , H110825 H110838 , H110786 H111057 , H110708 H110709 , A110130 A110204 , H111059 , A110142 A110231 A110232 , A110272 , H111055 , A110686 A110694 H110700 H110701 H110703 H110704 H110705 H110706 H110715 H111001 , A110121 H110855 , A110158 A110183 , A110464 A110468 H110831 , A110213 , H110861 H111051 H111067 , A110418 A110421 H110773 H110789 , H110978 H111008 , A110090 H111038 , A110525 , H110828 H110832 , H110995 H111043 H111053 , A110281 H110791 H110792 H110793 H110794 H110797 , H110918 , A110678 A110692 A110695 A110590 A110591 A110593 A110595 A110596 H111016 A110588 , A110030 A110032 , A110520 A110521 A110524 H110903 H110904 , H110699 , A110055 A110150 A110203 H111061 , H110971 , A110280 A110293 , A110070 A110072 , A110091 , A110462 H111028 , A110283 , A110087 , H110867 H110872 , A110319 A110322 , H110869 H110877 , H111178 , A110258 A110259 A110501 H110779 H111156 H111158 H111162 A110331 , A110092 A110095 A110098 A110099 A110454 A110473 A110598 A110600 A110601 A110607 , H111054 H111060 H111075 H111076 , H111068 , A110034 A110035 A110037 A110039 , H110774 H110775 , H110826 H110830 ,

	A110652 A110669 H110805 , H110865 H110868 , A110169 H111002 H111032 .
Recalling Firm/ Manufacturer	Pentax of America Inc 3 Paragon Dr Montvale NJ 07645-1782
For Additional Information Contact	Charlie Toms 800-451-5880 Ext. 2064
Manufacturer Reason for Recall	The duodenoscopes are being recalled in order to replace the forceps elevator mechanism, the O-rings, and the distal end covering to be consistent with the updated design as well as provide an updated periodic inspection as part of the Operation Manual in order to mitigate the potential risk of infection in flexible endoscopy.
FDA Determined Cause [2]	Device Design
Action	Pentax Medical sent an Urgent Medical Device Correction/Removal letter dated February 7, 2018, to the United States Customers. The consignee letter includes a customer response form and a revised operator manual with the added recommended periodic maintenance. The letter requests the return of the form which includes an accounting of the devices (by serial number) owned by the facility. The firm is to contact the consignee to arrange return of the affected units and to provide loaner devices as needed. For further questions, please call 1 (800) 431-5880 ext. 2064.
Quantity in Commerce	559
Distribution	USA (nationwide) Distribution to the states of including Puerto Rico : AL, AZ, CA, CO, CT, DE, FL, GA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, NH, NJ, NV, NY, OH, OK, PA, TN, TX, UT, VA, WA, WI, WV and WY, and the District of Columbia.
Total Product Life Cycle	TPLC Device Report[28]

[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[29].
[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 = FDT and Original Applicant = PENTAX MEDICAL[30] 510(K)s with Product Code = FDT and Original Applicant = PENTAX MEDICAL COMPANY[31]

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