## Class 2 Device Recall Pentax Video Duodenscope

**Date Initiated by Firm**
February 13, 2018

**Create Date**
February 20, 2018

**Recall Status**
Open

**Recall Number**
Z-0643-2018

**Recall Event ID**
79237

**510(K) Number**
K161222, K092710

**Product Classification**
Duodenscope and accessories, flexible/rigid

**Product**
Pentax Video Duodenscope Model: ED-3490TK (UDI of design being recalled: 04561333232420)

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

<table>
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<th>Code</th>
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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161728

2/26/2018
### 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
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

### Total Product Life Cycle
TPLC Device Report

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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.

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)is with Product Code = FDT and Original Applicant = PENTAX MEDICAL
510(K)is with Product Code = FDT and Original Applicant = PENTAX MEDICAL COMPANY

Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/r1.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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