



July 9, 2018

PENTAX of America, Inc.  
William Goeller  
Vice President, Quality and Regulatory Affairs  
3 Paragon Drive  
Montvale, NJ 07645-1782

Re: K181522  
Trade/Device Name: PENTAX Medical ED3490TK Video Duodenoscope  
PENTAX Medical ED34-i10T Video Duodenoscope  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and Accessories  
Regulatory Class: II  
Product Code: FDT  
Dated: June 6, 2018  
Received: June 11, 2018

Dear William Goeller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jeffrey W. Cooper -S  
2018.07.09 11:30:02  
-04'00'

for  
Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K181522

Device Name  
PENTAX Medical ED3490TK Video Duodenoscope

Indications for Use (Describe)

The ED-3490TK, Video Duodenoscope, is intended to provide optical visualization (via a video monitor) of, 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. This instrument is introduced via the mouth when indications consistent with the need for procedure are observed in adult and pediatric populations.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Indications for Use

510(k) Number (if known)  
K181522

Device Name  
PENTAX Medical ED34-i10T Video Duodenoscope

### Indications for Use (Describe)

The PENTAX Duodenoscope ED34-i10T is intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts. These instruments are introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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### 510(k) Summary

**Submitter:** PENTAX of America, Inc.,  
HOYA Corporation PENTAX Division  
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Montvale, New Jersey 07645-1782

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**Date Prepared:** June 18, 2018

**Trade/Device Names:** PENTAX Medical ED3490TK Video Duodenoscope  
PENTAX Medical ED34-i10T Video Duodenoscope

**Common/Usual Name:** Video Duodenoscope

**Regulation Number:** 21 CFR Part 876.1500

**Regulation Name:** Endoscope and accessories

**Regulatory Class:** Class II

**Product Code:** FDT

**Predicate Device:** PENTAX ED-3490TK Video Duodenoscope (K161222, clearance received on February 7, 2018)

#### Device Description:

These Video Duodenoscopes must be used with a PENTAX compatible Video Processor (software controlled device). The endoscopes have a flexible insertion tube, a control body and umbilicus. The umbilicus provides connection to the video processor. The control body includes controls for up/down/left/right angulation, air/water delivery, suction and an accessory inlet port. The devices contain light carrying bundles to illuminate the body cavity and a charge couple device (CCD) to collect image data. The instruments contain a working channel through which biopsy devices or other devices may be introduced.

#### Intended Use/Indications for Use:

The ED-3490TK, Video Duodenoscope, is intended to provide optical visualization (via a video monitor) of, 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. This instrument is introduced via the mouth when indications consistent with the need for procedure are observed in adult and pediatric populations.

The PENTAX Duodenoscope ED34-i10T is intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts. These instruments are introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.



### **Comparison of Technological Characteristics**

The difference between the subject devices and the predicate devices are as follows:

- O-ring Thickness
- Elevator Link Concentricity

The proposed design change requirement for the ED3490TK was to demonstrate a minimum of 10% Compression Ratio for the O-rings used to seal the elevator channel. Through analysis, the modification has demonstrated a Compression Ratio that met the pre-determined acceptance criterion. This change applies to both the ED3490TK and the ED34-i10T.

### **Summary of Technology Characteristics:**

The technological characteristics of the modified ED-3490TK and ED34-i10T are functionally equivalent to the predicate device, the ED-3490TK.

There are no changes to materials, design, or manufacture of the modified PENTAX Medical ED3490TK and ED34i10T Video Duodenoscope devices, and only two mechanical dimensional changes to the O-rings, which also do not change in material composition or manufacturing process. These modifications do not impact the intended use, safety and/or effectiveness of the two devices.

The sealed elevator mechanism of the ED34-i10T can be accessed after removal of the single use, detachable and disposable distal cap compared with the permanently fixed cap of ED-3490TK. The detachable and disposable distal cap of ED34-i10T allows the user to access the back side of the elevator for reprocessing.

### **Performance Data:**

No performance standards or special controls applicable to these devices have been adopted under Section 513 or 514 of the Federal Food, Drug, and Cosmetic Act.

### **Substantial Equivalence Discussion:**

After analyzing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, performance characteristics, and constituent materials), labeling, and sterilization method, we conclude that the subject devices the ED3490TK and ED34-i10T Video Duodenoscope are substantially equivalent to the predicate ED-3490TK Video Duodenoscope. The ED3490TK and the ED-34i10T are as safe and effective as the predicate device and neither of the differences raise new questions of safety or effectiveness.