October 21, 2019

Pentax Medical
William Goeller
Vice President, Quality Assurance and Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K192280
Trade/Device Name: PENTAX Medical ED-3490TK Video Duodenoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FDT
Dated: August 21, 2019
Received: August 22, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Martha Betz, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192280

Device Name

PENTAX Medical ED-3490TK Video Duodenoscope

Indications for Use *(Describe)*

The PENTAX Medical 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.

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PENTAX Medical ED-3490TK Video Duodenoscope
Traditional 510(k) Premarket Notification

510(k) SUMMARY

PENTAX Medical ED-3490TK Video Duodenoscope

1. Submitter

PENTAX Medical
3 Paragon Drive
Montvale, NJ 07645

Phone: 201-571-2318
Facsimile: 201-571-2340

Contact Person: William Goeller

Date Prepared: October 16, 2019

2. Device

Name of Device:	PENTAX Medical ED-3490TK Video Duodenoscope
Common or Usual Name:	Duodenoscope And Accessories, Flexible/Rigid
Classification Name:	Endoscope and accessories
Classification Number:	21 C.F.R. § 876.1500
Regulatory Class:	II
Product Code:	FDT

3. Predicate Device

PENTAX Medical ED-3490TK Video Duodenoscope (K181522)

4. Device Description

The PENTAX Medical ED-3490TK Video Duodenoscope is used with a PENTAX compatible Video Processor (software controlled device). The duodenoscope has 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.

PENTAX Medical ED-3490TK Video Duodenoscope
Traditional 510(k) Premarket Notification

The subject device is identical to the predicate device. There are no changes to the design, specifications, or technological characteristics of the PENTAX Medical ED-3490TK Video Duodenoscope as described in the predicate device 510(k) Premarket Notification, K181522.

5. Indications for Use

The PENTAX Medical 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 indications for use of the subject and predicate devices are identical. There have been no changes to the indications for use for the PENTAX Medical ED-3490TK Video Duodenoscope as described in the predicate device 510(k) Premarket Notification, K181522.

6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the subject and predicate device are identical with the exception of improvements to the RIFU resulting from completion of a Human Factors study. The reprocessing manual was revised to promote user adherence and comprehension of the reprocessing instructions. The subject device has the same fundamental technology and operating principles of the predicate device. There are no differences in specifications, design, materials, or manufacture.

7. Performance Data

The purpose of this 510(k) Premarket Notification is to obtain clearance of revised reprocessing instructions for use (RIFU) for the PENTAX Medical ED-3490TK Video Duodenoscope. The RIFU has been modified from the previously cleared version to more readily support user comprehension of and adherence to the reprocessing instructions. The revision to the RIFU was based upon human factors testing conducted by PENTAX Medical.

The revision to the RIFU does not affect the biocompatibility, electrical safety, electromagnetic compatibility, software verification and validation, or performance testing for the scope. No additional performance testing has been performed and no performance standards or special controls applicable to this device have been adopted under Section 513or 514 of the Federal Food, Drug, and Cosmetic Act.

PENTAX Medical ED-3490TK Video Duodenoscope
Traditional 510(k) Premarket Notification

8. Conclusions

The subject PENTAX Medical ED-3490TK Video Duodenoscope is identical to the predicate PENTAX Medical ED-3490TK Video Duodenoscope. The intended use and indications for use, technological characteristics, and principles of operation are the same for both devices. The sole difference between the subject and predicate device is that the RIFU has been revised to more readily support user comprehension of and adherence to the reprocessing instructions. This has been supported by Human Factors testing which demonstrates that the revision to the RIFU does not raise new issues of safety or effectiveness and thus, the data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.