PENTAX
MEDICAL

APR 10 2014

510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92:

Date: 24 Jun 2013

Submitter: PENTAX Medical Company,
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Trade/Device Name: PENTAX Video Upper G.I. Scopes (EG Family)

Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10

Common/Usual Name: Gastroscope and Accessories, Flexible/Rigid

Regulation Number: 21 CFR Part 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS

Predicate Device: OLYMPUS Gastrointestinal Videoscope GIF TYPE H180 (K100584; dated Jul 2 2010)

Regulation Number: 21 CFR Part 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS

Device Description:

The PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 are used with a Video Processor.

The PENTAX Video Upper G.I. scopes (EG Family) are composed of the following main parts: an Insertion Portion, Control Body and PVE Connector.

The Insertion Portion is inserted into the body cavity of patient. The Insertion Portion includes the Distal End and Bending Section. The Objective Lens, Light Guide, Instrument Channel, Air/Water Nozzle, and Water Jet Nozzle are located on the Distal End of the Insertion Portion. The Control Body is held by the user's hand. The Control Body includes the Angulation Control Knob, Angulation Lock Knob/Lever, Air/Water Cylinder, Suction Cylinder, Remote Control Button, Magnification Control Lever, and Instrument Channel Inlet. The Air/Water Feeding Valve is attached to the Air/Water Cylinder, and the Suction Control Valve is attached to the Suction Cylinder. The Inlet Seal is attached to the Instrument Channel Inlet. The PVE Connector is connected to the Video Processor via an Electrical Contacts. The Bending Section is bent by the Angulation Control Knob to operate the endoscope angulation. The Angulation Lock Knob/Lever is used to adjust the rotation torque of the Angulation Control Knob.

The Air/Water Feeding System is used to deliver the air and water to the Objective Lens from the Air/Water Nozzle. When the hole at the top of Air/Water Feeding Valve is covered, the air is delivered. When the Air/Water Feeding Valve is pushed, the water is delivered.
The Suction Control System is used to suction the fluid and air in body cavity from the Instrument Channel. When the Suction Control Valve is pushed, the fluid and air are suctioned.
The Remote Button is used to operate the function of video processor and external device from the control body, as necessary.

The Magnification Control Lever is used to magnify the image on the video monitor, as necessary. As this magnification function is performed electrically, focus and depth of field do not change.

Endotherapy Device such as Biopsy Forceps is inserted from the Instrument Channel Inlet into the body cavity through the instrument channel.
The Water Jet System is used to stream forward the sterile water from Water Jet Nozzle.

The Light Guide of the Distal End is used to illuminate the body cavity by light which is carried through the Light Carrying Bundle. The Light Carrying Bundle guides the light from Light Guide Plug which is connected to the Light Source inside the Video Processor.

The CCD built into the Distal End receives reflected light (image data) from the body cavity, and sends the image data to the Video Processor through the video cable. The image data are converted into the image signal by the Video Processor, and the image inside the body cavity is displayed on the Monitor.

Intended Use:

This instrument is intended to be used with a PENTAX video processor (including light source), documentation equipment, monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.

Summary of Technology Characteristics

The PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 has the same fundamental technology and operating principles in comparison to those of the predicate device, including same intended use, design technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination. The minor differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between two devices do not impact the intended use, and do not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Safety and Performance Data (Non-clinical tests)

Design Verification and Validation testing has been performed in accordance with Design control per 21 CFR Part 820.30. The performance of the EG Family Master Device (EG-2990i) were evaluated using the appropriate methodology as specified in the following FDA recognized consensus standards in conjunction with our in-house test protocols and use of external testing laboratories:

1. IEC 60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-1:2000 Medical electrical equipment- Part 1-1: General requirements for safety- Collateral standard: Safety requirements for medical electrical systems
3. IEC 60601-1-2:2001+A1:2004 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4. ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization
7. IEC 60601-2-18:1996+A1:2000 Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
8. ISO 8600-1:2005 Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements
9. ISO 8600-3:1997+A1:2003 Optics and optical instruments –Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics

10. ISO 8600-4:1997 Optics and optical instruments -Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
11. AAMITIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
12. AAMITIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
13. ANSI/AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
14. IS013485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
15. ISO 14971:2007 (corrected version): Medical devices -Application of risk management to medical devices
16. IEC 60601-1-4:2000 Ed. 1.1 Medical electrical equipment- Part 1-4: General requirements for safety- Collateral Standard: Programmable electricalmedical systems
17. IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
18. IEC 62366:2007 Medical devices -Application of usability engineering to medical devices
19. IEC 62304:2006 Medical device software- Software life cycle processes
20. IEC 604171SO 7000-DB-12M:2004 Graphical symbols for use on equipment- 12-month subscription to online database comprising all graphical symbols published in IEC 60417 and ISO 7000
21. ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
22. IEC 60878:2003 Graphical symbols for electrical equipment in medical practice

The PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 Master Device (EG-2990i) test results satisfy the acceptance criteria specified by the above applicable standards.

Biocompatibility Test

Biocompatibility of direct and indirect contact materials were confirmed by testing the Cytotoxicity, Sensitization and Intracutaneous Reactivity for the surface device, mucosal membrane contact less than 24 hours duration device category in accordance with the ISO 10993-1, 5, and 10 Biological evaluation of medical devices standard and the FDA's guidance the Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'.

Reprocessing Validation

Simulated use conditioned test samples were used in the Cleaning validation and High Level Disinfection validation studies for validating the effectiveness of the reusable Bronchoscope Reprocessing procedures/methodology in accordance with the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011, AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A

guide for device manufacturers, AAMI TIR 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, and AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. All the study results satisfy the acceptance criteria specified by the above applicable standards.

In addition, the Reprocessing Instructions (Manual) were validated based on the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011. The validation confirmed that the PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 Reprocessing Instructions are complete, understandable, and can reasonably be executed by the user.

EMC and Electrical Safety

The acceptable level of Electromagnetic compatibility (EMC) and Electrical Safety (ES) for the PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 were confirmed by testing in accordance with the IEC 60601-1; IEC 60601-1-2; IEC 60601-1-4; IEC 60601-1-6; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Safety requirements for medical electrical systems, Electromagnetic compatibility - Requirements and tests; and IEC 60601-2-18:1996+A1:2000 Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Substantial Equivalence discussion:

The PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 has the same intended use, fundamental technology and operating principles including design technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination in comparison to those of the predicate device. The minor dimensional differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between two devices do not impact the intended use, and do not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Conclusion:

The PENTAX Medical Company believes that the PENTAX Video Upper G.I. scopes (EG Family), Model Numbers: EG-2990i, EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG-2990K, EG-3490K, EG-3890TK, EG27-i10, EG29-i10 as indicated in this 510(k) premarket notification submission is to be as safe, as effective and substantially equivalent in performance to the above identified cleared predicate device/system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

PENTAX Medical
Krishna Govindarajan
Regulatory Affairs, Americas
3 Paragon Drive
Montvale, NJ 07645

Re: K131902
Trade/Device Name: PENTAX Video Upper G.I. Scopes (EG Family)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated: April 3, 2014
Received: April 4, 2014

Dear Krishna Govindarajan,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131902

Device Name
PENTAX Video Upper G.I. Scopes (EG Family)

Indications for Use *(Describe)*

This instrument is intended to be used with a PENTAX video processor (including light source), documentation equipment, monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.04.10 12:36:49 -04'00'

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