

JUN 22 2012



Section 5: 510(k) Summary

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

Date: 28 Dec 2011

Submitter: PENTAX Medical Company,
A Division of PENTAX America, Inc.
3 Paragon Drive
Montvale, New Jersey 07645-1782

Contact: Krishna Govindarajan
Regulatory Manager
PENTAX Medical Company,
A Division of PENTAX America, Inc.
3 Paragon Drive
Montvale, New Jersey 07645-1782
Phone: 800-431-5880 x 2125, 201-251-2300 x 2125
Fax: 201-799-4117
Email: Krishna.govindarajan@pentaxmedical.com

Device – Trade Name: PENTAX EPK-i5020 Video Processor

Common/Usual Name: Endoscopic Video Processor and Light Source

Classification Name: Endoscopic video imaging system/component, gastroenterology-urology

Regulation Number: 21 CFR Part 876.1500
Regulation Description: Endoscope and accessories
Medical Specialty: Gastroenterology/Urology
Regulatory Class: Class II
Product Code: FET and GCT

Predicate Device: Fujinon EPX-4440HD Digital Processor and Light Source
(K102466 dated May 25, 2011)

Device Description:

The EPK-i5020 Video Processor consists of light source with 300 W Xenon Lamp to provide illumination, video processor to convert data from video endoscope into standard video output for visualization via video monitor, and interfacing with external peripheral devices. The processor controls the lamp brightness, white and color balance adjustments, and air pump to supply air through the video endoscope to help clear visualization. In addition, the EPK-i5020 Video Processor indicates the operating status and lamp life in the front panel. This device operates with 120 ±10% VAC, 50 - 60 Hz power supply.

PENTAX

PENTAX Medical Company
A Division of PENTAX of America, Inc.

Intended Use:

The EPK-i5020 Video Processor is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to be used with PENTAX Video Endoscopes to provide illumination, control air pump to supply air through the video endoscope to help clear visualization, convert data from video endoscope into standard video output for visualization via video monitor, and interfacing with external peripheral devices.

Technology Characteristics:

The EPK-i5020 Video Processor has the same fundamental scientific technology as commercially available endoscope video processor and the substantially equivalent predicate device.

Substantial Equivalence Determination:

1. Summary of Nonclinical Tests

The PENTAX EPK-i5020 Video Processor complies with voluntary standards as detailed in this premarket notification submission. The following quality assurance measures were applied to the design and development:

- Risk Management (Analysis & Mitigation)
- Requirements Reviews
- Design Reviews
- Unit Testing (Software & Hardware Verification)
- Integration testing (Software & Hardware Verification)
- Performance testing (Software & Hardware Verification)
- Safety testing (System level Verification & Validation)
- Simulated use testing (System level QA Validation)
- Electrical testing according to IEC 60601
- Software validation performed in accordance with IEC 62304

2. Summary of Clinical Tests

Not Applicable to support substantial equivalence.

3. Conclusion

The PENTAX Medical Company believes that the intended use of the EPK-i5020 Video Processor as indicated in this premarket notification submission is to be as safe, as effective and substantially equivalent in performance to the above identified predicate devices.



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

JUN 22 2012

PENTAX of America, Inc.
% Robert Schiff, Ph.D.
President and CEO
Schiff & Company, Inc.
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

Re: K113873
Trade/Device Name: EPK-i5020 Video Processor
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, GCT
Dated: May 30, 2012
Received: May 31, 2012

Dear Dr. Schiff:

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.

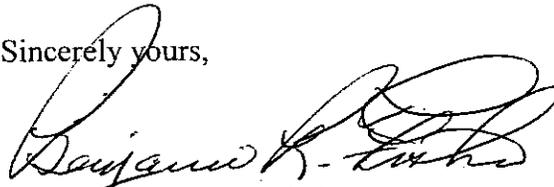
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



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): K113873

Device Name: EPK-i5020 Video Processor

Indications For Use:

The EPK-i5020 Video Processor is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to be used with PENTAX Video Endoscopes to provide illumination, control air pump to supply air through the video endoscope to help clear visualization, convert data from video endoscope into standard video output for visualization via video monitor, and interfacing with external peripheral devices.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K113873