

PENTAXPENTAX Medical Company
A Division of PENTAX of America, Inc.**MAR 20 2013****510(k) Summary**

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

Date: 28 February 2013

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.
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Device – Trade Name: PENTAX EG-3670URK Ultrasound Video Gastroscope (Radial Array Type) + HI VISION PREIRUS

Common/Usual Name: Endoscopic Ultrasound

Classification Name: Endoscopic ultrasound system, gastroenterology/urology

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

Predicate Device: PENTAX EG-3670URK Ultrasound Video Gastroscope + HI VISION 900 (K090196)

Intended Use:

The EG-3670URK, Ultrasound Video Gastroscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

PENTAXPENTAX Medical Company
A Division of PENTAX of America, Inc.**Device Description:**

PENTAX EG-3670URK Ultrasound Video Gastroscope + HI VISION PREIRUS are the endoscopic ultrasound system consists of an ultrasound endoscope with a radial array type ultrasound transducer, video processor, and Hitachi ultrasound scanner. This modified new system configuration is to work together with the already cleared latest Hitachi HI VISION PREIRUS Diagnostic Ultrasound Scanner (K093466).

Device Modification & Substantial Equivalence:

The PENTAX EG-3670URK Ultrasound Video Gastroscope with HITACHI Hi VISION 900 (HV900) Ultrasound Scanner system configuration has been previously cleared (K090196). This Special 510(k) submission is a modification with new system configuration to work together with the already cleared latest Hitachi HI VISION PREIRUS Diagnostic Ultrasound Scanner (K093466) instead of old Hitachi HI VISION 900 Diagnostic Ultrasound Scanner (K063518).

There are no software or hardware changes between the PENTAX EG-3670URK Ultrasound Video Gastroscope subject and predicate device in connecting with the new Hitachi HI VISION PREIRUS Diagnostic Ultrasound Scanner. In addition, there are no change in technology, including features, materials, and principles of operation.

The system configuration modification does not impact the intended use, safety and/or effectiveness. The modified system configuration has been verified and validated according to the company's design control activities as certified in this Special 510(K) Submission's declaration of conformity with design control to ensure the compatibility between the PENTAX EG-3670URK Ultrasound Video Gastroscope and the HITACHI HI VISION PREIRUS Ultrasound Scanner.

This modified system configuration is substantially equivalent to the predicate device/system with regards to both intended use and technological characteristics.

Conclusion:

The PENTAX Medical Company believes that the PENTAX EG-3670URK Ultrasound Video Gastroscope + HI VISION PREIRUS system modification as indicated in this special 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.



March 20, 2013

PENTAX Medical
A Division of PENTAX America, Inc.
% Mr. Krishna Govindarajan
Regulatory Manager
3 Paragon Drive
MONTVALE NJ 07645

Re: K130206

Trade/Device Name: PENTAX EG-3670URK Ultrasound Video Gastroscope
(Radial Array Type) + HI VISION PREIRUS

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: ODG and ITX

Dated: March 1, 2013

Received: March 4, 2013

Dear Mr. 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.

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

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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 contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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,



for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K130206**

Device Name: **PENTAX EG-3670URK Ultrasound Video Gastroscope (Radial Array Type) + HI VISION PREIRUS**

Indications for Use:

Endoscope

The EG-3670URK, Ultrasound Video Gastroscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Diagnostic Ultrasound

System: Hitachi HI VISION PREIRUS

Probe: EG-3670URK (Radial Array Type)

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application		Mode of Operation					
General (Track I only)	Specific (Track I & II)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic							
Fetal Imaging and other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laposcopic						
	Pediatric						
	Small Organ						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vagina						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convert.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N = new application; **P = previously cleared by FDA; K090196** E = added under Appendix E

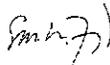
Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130206