510(k) Summary

K090196

Submitter Information: Pentax Medical Company, A Division of Pentax America, Inc.
102 Chestnut Ridge Road
Montvale, New Jersey 07645-1856

MAY 19 2009

Name of Device

Trade Name:	EG-3670URK, Ultrasound Video Gastroscope
Classification Name:	Endoscopic Ultrasound System, Gastro-Urology (78ODG) {876.1500}; track3, tier2

Predicated Device(s) Information

Model, Description	Manufacturer	PMN #
EG-3670URK, Ultrasound Video Gastroscope	Pentax Corporation	K061068
Hi Vision 900 Diagnostic Ultrasound Scanner	Hitachi	K063518

Device Description

The EG-3670URK, Ultrasound Video Gastroscope, must be used with a Pentax Video processor (a software controlled device) and must be used with an Ultrasound Scanner (a software controlled device). The endoscope has a flexible insertion tube, a control body, PVE umbilical connector, and ultrasound scanner umbilical connector. The PVE connector will be attached to the Video Processor and has connections for illumination, video signals, air/ water/ and suction. The ultrasound umbilical connector will be attached to the ultrasound scanner unit. The control body includes controls for up/ down/ left/ right angulation, air/ water delivery, suction selection control, balloon insufflation/ evacuation, and an accessory inlet port. The endoscope contains light carrying bundles to illuminate the body cavity, a charge couple device (CCD) to collect endoscopic image data, and a radial array ultrasound transducer to collect ultrasonic image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced. The video processor contains a lamp that provides white light and is focused at the PVE connector light guide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects endoscopic image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display. The ultrasound transducer delivers ultrasonic pulses, reflections of the pulses are received and the signals are passed to the ultrasound scanner for processing and display. The instrument is immersable (with the use of supplied cleaning accessories) except for the ultrasound scanner connector (as described in the endoscope operator manual cleaning instructions).

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.

Comparison to Predicated Device(s)

The submission for substantial equivalence was made to allow the use of the 510k cleared endoscope, EG-3670URK, with the 510k cleared ultrasound scanner, Hi Vision 900. The submission included mechanical drawings, material lists, labeling, the identification of standard set components and optional accessories, tables to summarize the comparisons to the predicated device(s), and system performance testing, and acoustic power data. The submission for substantial equivalence is not based on an assessment of clinical performance data.

Prepared by: Paul Silva Signature: Paul Silva Date: 01.24.2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Mr. Paul Silva
Director of Regulatory Affairs
PENTAX Medical Company
102 Chestnut Ridge Road
MONTVALE NJ 07645-1856

Re: K090196
Trade/Device Name: EG-3670URK Ultrasound Video Gastroscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODG and ITX
Dated: January 24, 2009
Received: February 4, 2009

Dear Mr. Silva:

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 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.

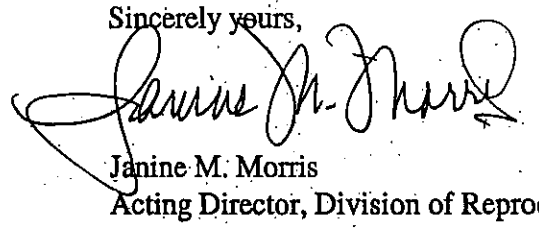
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090196

Device Name: EG-3670URK, Ultrasound Video Gastroscope

Endoscope Intended Use Statement

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 Indications For Use Statement

System: Hi Vision 900

Probe: EG-3670URK

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 & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic							
Fetal Imaging and other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laproscopic						
	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	N	N	N		N	N
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

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Prescription Use (Per 21 CFR 801.109)