K013640

510(k)Summary
EG-3630UR, Ultrasound Video Gastroscope
for use with EUB-525 and EUB-6000 Ultrasound Diagnostic Scanner

FEB 0 4 2002

Submitter Information: Pentax Precision Instrument Corporation (PPIC)
30 Ramland Road
Orangeburg, NY, 10962
Tel: (845)-365-0700

Name of Device:

Trade Name:	EG-3630UR, Ultrasound Video Gastroscope
Classification Name:	Diagnostic Ultrasound Transducer (74JOP) {892.1570}, Endoscope and Accessories (78KOG) {876.1500}

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN#
FG-36UX, Fiber Ultrasound Gastroscope	PPIC	K961974
EG-2940, Video Gastroscope	PPIC	K961564
EPM-3300, Video Processor	PPIC	K934918
EUB-525, Ultrasound Diagnostic Scanner	Hitachi America	K981434
EUB-6000, Ultrasound Diagnostic Scanner	Hitachi America	K994026

Device Description: The EG-3630UR, Ultrasound Video Gastroscope, must be used with a Pentax Video Processor (software controlled device) and must be used with Ultrasound Scanner (software controlled device). The endoscope has a Flexible Insertion Tube, a Control Body, PVE Umbilical Connector, and Scanner Umbilical Connector. The PVE Connector connects to the Video Processor and has connections for illumination, video signals, air/water and suction. The Scanner Connector is connected at the Ultrasound Scanner. The Control Body includes controls for up/ down/ left/ right angulation, air/water delivery, suction selection/ control, balloon insufflation, and an accessory inlet port. The device contains light carrying bundles to illuminate the body cavity, a charge couple device (CCD) to collect 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 instrument is supplied with two biopsy forceps). The Video Processor contains a lamp that provides white light that is filtered, via a Red, Green, and Blue color filter wheel, and is focused at the PVE Connector Lightguide Prong. The endoscope light carrying bundles present the color strobes to the body cavity and the CCD collects image data for each strobe of color. The Video Processor stores the CCD information until all three color strobes are completed and a full color image frame is compiled. 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 signals are passed to the Ultrasound Scanner for 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-3630UR, Ultrasound Video Gastroscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes but is 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 the procedure are observed in adult and pediatric patient populations.

Comparison To Predicated Device(s):
The submission for substantial equivalence included EG-3630UR literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices in summary. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Prepared by: Paul Silva Signature: Paul Silva Date: 11-01-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Mr. Paul Silva
Regulatory Affairs Coordinator
PENTAX Precision Instrument Corp.
30 Ramland Road
ORANGEBURG NY 10962-2699

Re: K013640
Trade/Device Name: Ultrasound Video Gastroscope EG-3630UR
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Procode: 76 FDS
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasound transducer
Procode: 90 ITX
Dated: November 1, 2001
Received: November 5, 2001

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.

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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013640

Device Name: Ultrasound Video Gastroscope EG-3630UR

Indications For Use: The Ultrasound Video Gastroscope EG-3630UR is intended to provide ultrasonic and optical visualization of, and therapeutic access to, the Upper GI tract including esophagus, stomach, duodenum/small bowel in adult and pediatric patient populations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013640

(Optional Format 3-10-98)

Prescription Use