K041396

JUN - 9 2004

510(k)Summary
FG-36UX, Fiber Ultrasound Gastroscope
for use with EUB-5500 and EUB-8500 Ultrasound Diagnostic Scanner

Submitter Information: Pentax Precision Instrument Corporation (PPIC)
30 Ramland Road
Orangeburg, NY, 10962
Tel: (914)-365-0700

Name of Device:

Trade Name	FG-36UX, Fiber Ultrasound 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
EUB-5500, Ultrasound Diagnostic Scanner	Hitachi America	K032503
EUB-8500, Ultrasound Diagnostic Scanner	Hitachi America	K013722

Device Description: The FG-36UX, Fiber Ultrasound Gastroscope, can be used with any Lightsource (with the appropriate lightguide receptacle) and must be used with Ultrasound Scanner (software controlled device). The endoscope has a flexible insertion tube, a control body, and Umbilicus . The umbilicus is bifurcated where one connector is connected to the Lightsource and contains connections for air/water and suction. The other umbilicus bifurcation is connected at the ultrasound scanner. The control body includes controls for up/ down/ left/ right angulation, an accessory elevator control, air/water delivery, suction selection/ control, forward water jet port, balloon insulflation, an accessory inlet port, and the endoscopic image viewing occular. The device contains light carrying bundles, one to illuminate the body cavity another to optically visualize the anatomy, and an 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). A convex linear array 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 FG-36UX, Fiber Ultrasound 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 FG-36UX 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: 11-25-2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2004

PENTAX Precision Instrument Corporation
% Mr. Matthias Heinze
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K041396
Trade Name: EUB-5500 and EUB 8500 Ultrasound Diagnostic Scanners
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 90 ITX and 78 FDS
Dated: May 21, 2004
Received: May 26, 2004

Dear Mr. Heinze:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-5500 and EUB 8500 Ultrasound Diagnostic Scanners, as described in your premarket notification:

Transducer Model Number

FG-36UX

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. 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 at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for

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

Enclosure(s)

510(k) Number (if known):_____
Device Name: Ultrasound Video Gastroscope FG-36UX

Endoscope Intended Use Statement:
The FG-36UX, Fiber Ultrasound 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.

Diagnostic Ultrasound Indications For Use Statement
System: EUB-8500
Probe: FG-36UX
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 & 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. (Convent.)						
	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

(Please do not write below this line – continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041396

Prescription Use (Per 21 CFR 801.109)

510(k) Number (if known):_____
Device Name: Ultrasound Video Gastroscope FG-36UX

Endoscope Intended Use Statement:
The FG-36UX, Fiber Ultrasound 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.

Diagnostic Ultrasound Indications For Use Statement
System: EUB-5500
Probe: FG-36UX
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 & 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. (Convent.)						
	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

(Please do not write below this line – continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041396

Prescription Use (Per 21 CFR 801.109)