

JUL 27 1998

Hitachi EUP-OL334 Laparoscopic Probe
used with EUB-525/-555 and EUB-8000 Systems

K981434

April 17, 1998

SUMMARY OF SAFETY AND EFFECTIVENESS
Hitachi EUP-OL334 Laparoscopic Probe

Device Description

The Hitachi EUP-OL334 Laparoscopic Probe is a Track 3 diagnostic ultrasound transducer capable of the following operating modes: B, M, Pulsed Doppler, and Color Flow (including Amplitude Doppler). It is intended for laparoscopic clinical applications with the EUB-525, EUB-555, and EUB-8000 Hitachi Diagnostic Ultrasound Systems.

Safety

As a Track 3 ultrasound device, the Hitachi EUP-OL334 Laparoscopic Probe complies with the "Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992)", published by the National Electrical Manufacturers Association as UD-3. With respect to limits on acoustic outputs, the Hitachi EUP-OL334 Laparoscopic Probe complies with the guideline limits set in the April 14, 1994, Revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Hitachi EUP-OL334 Laparoscopic Probe is designed to comply with IEC 601-1 (1988) Medical Electrical Equipment, Part 1, General Requirements for Safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 27 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Charles F. Hottinger
Hitachi Medical Corp. of America
19030 Portos Drive
Sarátoga, CA 95070

Re: K981434
Trade Name: Hitachi EUP-OL334 Laparoscopic Probe
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: July 16, 1998
Received: July 17, 1998

Dear Mr. Hottinger:

We have reviewed your Section 510(k) 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 Hitachi EUP-OL334 Laparoscopic Probe, intended for use with the following Hitachi diagnostic ultrasound systems, as described in your premarket notification:

System Model Number

EUB-555
EUB-525
EUB-8000

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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

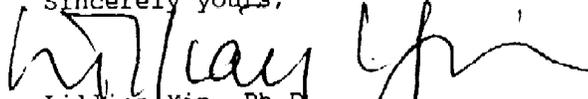
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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>".

Page 3 - Charles F. Hottinger

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin", written in a cursive style.

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K981434

Hitachi EUP-OL334 Laparoscopic Probe
used with EUB-525/-555 and EUB-8000 System

April 17, 1998

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-555/-525; EUB-8000

Transducer: EUP-OL334

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other* (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N		N		N
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

* Amplitude Doppler

Additional Comments: EUB-555 previously cleared under K926209; EUB-525 marketed as a modification to EUB-555 under Appendix I of the Feb. 17, 1993, ultrasound 510(k) guidance. EUB-8000 previously cleared under K954220.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

William J. ...

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

510(k) Number K981434

K981434

Hitachi EUP-OL334 Laparoscopic Probe
used with EUB-525/-555 and EUB-8000 System

April 17, 1998

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM (amended July 15, 1998)

System: EUB-555/-525
Transducer: All cleared probes + EUP-OL334

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other* (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P		E
	Abdominal	Pa	P	P	P	P		E
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb		E
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N		N		N
	Pediatric	P	P	P	P	P		E
	Small Organ (Spec.)	Pc	Pc	Pc		Pc		E
	Neonatal Cephalic	P	P	P		P		E
	Adult Cephalic							
	Trans-rectal	Pd	P	P		P		E
	Trans-vaginal	Pe	P	P		P		E
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other: Urology		P	P	P		P		E
Other: Gynecology		P	P	P		P		E
Other (spec.)								
Cardiac	Cardiac Adult	P	P	P	P	P		E
	Cardiac Pediatric	P	P	P	P	P		E
	Trans-esophageal (card.)	P	P	P		P		E
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P		E
	Other (spec.)							

N= new indications for EUP-OL334; P= previously cleared by FDA under K926208; E= added under Appendix I of the Feb. 17, 1993 guidance. * Amplitude Doppler
Additional Comments: EUB-525 marketed as a modification to EUB-555 under Appendix I of the Feb. 17, 1993 guidance; "E": Amplitude Doppler cleared with the EUB-8000 under K954220.
"Pa": includes imaging for guidance of percutaneous biopsy of abdominal organs and structures;
"Pb": includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures; "Pc": includes thyroid, parathyroid, breast, scrotum, and penis;
"Pd": includes imaging for guidance of trans-rectal biopsy;
"Pe": includes imaging for guidance of trans-vaginal biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981434

K981434

Hitachi EUP-OL334 Laparoscopic Probe
used with EUB-525/-555 and EUB-8000 System

April 17, 1998

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-8000

Transducer: All cleared probes + EUP-OL334

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other* (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P		P
	Abdominal	Pa	P	P	P	P		P
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb		Pb
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N		N		N
	Pediatric	P	P	P	P	P		P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc		Pc
	Neonatal Cephalic	P	P	P		P		P
	Adult Cephalic							
	Trans-rectal	Pd	P	P		P		P
	Trans-vaginal	Pe	P	P		P		P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)								
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult	P	P	P	P	P		P
	Cardiac Pediatric	P	P	P	P	P		P
	Trans-esophageal (card.)	P	P	P		P		P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P		P
	Other (spec.)							

N= new indications for EUP-OL334; P= previously cleared by FDA under K954220. * Amplitude Doppler

Additional Comments: "Pa": includes imaging for guidance of percutaneous biopsy of abdominal organs and structures; "Pb": includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures; "Pc": includes thyroid, parathyroid, breast, scrotum, and penis; "Pd": includes imaging for guidance of trans-rectal biopsy; "Pe": includes imaging for guidance of trans-vaginal biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K981434