DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1997

Raul Gutierrez, R.T., R.D.M.S.
President
International Ultrasound Corporation
14 West Forest Avenue
Englewood, NJ 07631

Re: K961229
HRI 2000 Ultrasound System
Dated: March 28, 1997
Received: March 28, 1997
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Gutierrez:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number			
GA-3.5	(CLI 7900)	3.5 MHz	General Purpose
TV-6.5	(CLI 4000)	6.5 MHz	Transvaginal
TR-6.5	(CLI 5000)	6.5 MHz	Transrectal
PV-12.5	(CLI 6000)	12.5 MHZ	Peripheral Vascular

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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." 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".

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

Sincerely yours,

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

510(k) Number (if known): K961229

Device Name: HRI2000 Ultrasound System

Indications For Use:

The HRI2000 system connected with a probe enables real time two dimensional diagnostic ultrasound imaging. The system offers optional probes each type optimized to image structure and orienation of tissues during specific clinical applications. These include general abdominal, small organ, gynecological and urological, vascular and cardiac anatomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Segen

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K961729

510(k) Number (if known): K961229
Device Name: CLI 7900 GP 3.5 MHz Probe

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		X								
Intra-operative (Specify)										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult		X								
Cardiac Pediatric		X								
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K961229

Page_____of_____

510(k) Number (if known): K961229
Device Name: CLI 4000 TV 6.5 MHz Probe

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal		X								
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Harold A. Segnon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K961229

Page_____of_____

510(k) Number (if known): K961129
Device Name: CLI 5000 6.5 MHz Probe

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal		X								
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
CONCURRENCE OF CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K961229

Page_____of_____

510(k) Number (if known): K961229
Device Name: CLI 6000 PV 12.5 MHz Probe

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Pediatric										
Small Organ (Specify)		X								
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X		X						
Laparoscopic										

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K961229