K051334

JUN 3 2005

510(k) Summary
TERATECH Corporation TERASON™ Ultrasound System with Continuous Wave (CW) Doppler

1. **SPONSOR**

TERATECH Corporation
77-79 Terrace Hall Rd.
Burlington, MA 01803

Contact Person: Charles F. Hottinger, Ph.D., RAC,
Regulatory Affairs Consultant

Telephone: 206-780-7945

Date Prepared: May 11, 2005

2. **DEVICE NAME**

Proprietary Name: TERASON™ UltrasoundSystem withContinuous Wave (CW) Doppler

Common/Usual Name: Diagnostic Ultrasound System

Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. **PREDICATE DEVICES**

Toshiba Powervision 6000 (K991710)

4. **INTENDED USE**

The TERASON™ Ultrasound System with Continuous Wave (CW) Doppler is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body; specific indications for use a tabulated in Section 4.3 of this

submission.

5. Device Description

The TERASON™ Ultrasound System with Continuous Wave (CW) Doppler introduces two new versions of the TERATECH Model 2000 Imaging System.

	TERATECH 2000	TERASON™ t3000	TERASON™ Echo
Transmit: Receive Beam forming Channels	128:64	128:64	128:128
CW Doppler	No	Yes	Yes
ECG Trigger	No	Yes	Yes
Tissue Doppler	No	No	Yes
LV Dyssynchrony Assessment	No	No	Yes

6. Basis for Substantial Equivalence

The TERASON™ Ultrasound System is substantially equivalent to the Toshiba Powervision 6000, which is currently in commercial distribution in the United States. Since it is identical in modes of operation, and intended for the same clinical applications, as described in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 2005

TERATECH Corporation
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K051334
Trade Name: TERASON Ultrasound System with Continuous Wave Doppler
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 19, 2005
Received: May 23, 2005

Dear Mr. Job:

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 TERASON Ultrasound System with Continuous Wave Doppler, as described in your premarket notification:

Transducer Model Number

4C2
4V2

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: TERASON™ Ultrasound System

Transducer: (see comments)

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 (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Abdominal[d]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Intra-operative (Spec.)[d,e]	P[4]	P[4]	P[4]		P[4]	P[4]	P[4]
	Intra-operative (Neuro)	P[5]	P[5]	P[5]		P[5]	P[5]	P[5]
	Laparoscopic	P[6]	P[6]	P[6]		P[6]	P[6]	P[6]
	Pediatric[d]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Neonatal Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Adult Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Trans-rectal[f]:	P[2,4]	P[3,4]	P[3,4]		P[3,4]	P[3,4]	P[3,4]
	Trans-vaginal[g]:	P[2,4]	P[3,4]	P[3,4]		P[3,4]	P[3,4]	P[3,4]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Musculo-skel. (Superfic)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Cardiac Pediatric	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Other (Specify)							

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

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal organs and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

[1] System uses previously cleared under K992505 with 3 MHz Model L3 (Linear).

[2] System uses previously cleared under K012191.

[3] System uses previously cleared under K010883.

[4] System uses previously cleared under K030191.

[5] System uses previously cleared under K040840.

[6] System uses previously cleared under K043278.

Includes uses in military field settings in addition to hospital/clinic settings.

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

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051334

System: TERASON™ Ultrasound System

Transducer: 4C2

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 (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Abdominal[d]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N[1]	N[2]	N[2]	N	N[2]	N[2]	N[2]
	Cardiac Pediatric	N[1]	N[2]	N[2]	N	N[2]	N[2]	N[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

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[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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510(k) Number K051334

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	Intra-operative (Neuro)							
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	Pediatric[e]:	P[1,4]	P[2,4]	P[2,4]	N	P[2,4]	P[2,4]	P[2,4]
	Small Organ (Thyroid, Breast, Testes, etc.)[e]:							
	Neonatal Cephalic[e]:	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Adult Cephalic[e]:	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Cardiac Pediatric	P[1]	P[2]	P[2]	N	P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053334