APR 1 4 2004

K040840
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510(k) Summary for
TERATECH Model 10V5 Smart Probe

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: March 8, 2004

2. DEVICE NAME

Proprietary Name: TERATECH Model 10V5 Smart Probe

Common/Usual Name: Diagnostic Ultrasound Transducer

Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

Acuson 10V4 Sequoia™ Ultrasound System and Harmonic Imaging (K97367)
Acuson Aspen™ Ultrasound System (K991805)

4. INTENDED USE

The TERATECH Model 10V5 Smart Probe 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 TERATECHModel 10V5 Smart Probe is intended for use with the Model TERATECH 2000 , a portable ultrasound imaging system. Technical

specifications for the Model 10V5 Smart Probe with the Model 2000 are as follows:

Probe Description (Frequency / Elements)	Array Type	Pitch (mm)	Elevation Width (mm)	Geometric Focus (mm)	Azimuth Radius (mm)	Azimuth Length (mm)
7 Mhz /128	Phased	0.110	6.0	36.5	Flat	14.1

7. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TERATECH Model 10V5 Smart Probe is substantially equivalent to the Acuson 10V4, which is currently in commercial distribution in the United States. The TERATECH Model 10V5 Smart Probe is identical in design and materials to the Acuson 10V4; when operated with the TERATECH Model 2000 portable imaging system, the Model 10V5 has intended uses and a mode of operation which are a subset of those of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

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

Re: K040840
Trade Name: Model 10V5 Smart Probe
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: Class II
Product Code: 90 ITX
Dated: March 29, 2004
Received: April 1, 2004

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 Model 10V5 Smart Probe, as described in your premarket notification:

Transducer Model Number

10V5 Smart Probe

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 David A. Lyon

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

Enclosure

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000 Portable 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]		P[2,4]	P[2,4]	P[2,4]
	Intra-operative (Spec.)[d,e]	P[1,4]	P[4]	P[4]		P[4]	P[4]	P[4]
	Intra-operative (Neuro)	N	N	N		N	N	N
	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]:	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]		P[2,4]	P[2,4]	P[2,4]
	Adult Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]		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]		P[2]	P[2]	P[2]
	Cardiac Pediatric	P[1]	P[2]	P[2]		P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:	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.

Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear); P[2]: uses previously cleared under K012191; P[3]: uses previously cleared under K010883; P[4]: uses previously cleared under K030191

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)

David G. Lyon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040840

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	Intra-operative (Neuro)	N	N	N		N	N	N
	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	P[1]	P[2]	P[2]		P[2]	P[2]	P[2]
	Cardiac Pediatric	P[1]	P[2]	P[2]		P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	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.
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Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear); P[2]: uses previously cleared under K012191; P[3]: uses previously cleared under K010883; P[4]: uses previously cleared under K030191
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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
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