K030191

JAN 2 9 2003

510(k) Summary for TERASON™ Model 2000/BAS Portable Ultrasound System

1. SPONSOR

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

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

Telephone: 408-741-1006

Date Prepared: December 16, 2002

2. DEVICE NAME

Proprietary Name: TERASON™ Model 2000/BAS Portable Ultrasound Systems

Common/Usual Name: Ultrasound System and Transducers

Classification Name: Ultrasonic Pulsed Doppler Imaging System
(21 CFR 892.1550, 90 IYN)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90 IYO)
Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

(1): Teratech Corp. TERASON™ 2000 Handheld Ultrasound System
K012191
Date Cleared: July 26, 2001

(2): ATL HDI™ 1500 Diagnostic Ultrasound System and Transducers
K994373
Date Cleared: May 24, 2000

(3) Dymax Corp. Site-Rite 3 Ultrasound Scanner
K993624
Date Cleared: November 10, 1999

4. INTENDED USE

The TERASON™ Model 2000/BAS Portable Ultrasound Systems are 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

Technical specifications for the TERASON™ Model 2000/BAS Portable Ultrasound Systems are as follows:

System

Transducer frequencies:	2-4 MHz (4C2 and 4V2), 4-8 MHz (8EC4, 8L4)
Frame rate:	15 - 58 fps (Imaging only)
Ultrasound lines/frame:	128
Fields of View:	2.5 - 24 cm
External Video Output:	Composite Video, VGA Monitor
Liquid-Crystal Display:	10.4" XVGA TFT
Size: Width:	11.6"
Height:	9.3"
Depth:	1.65"
Weight: Laptop Computer	4.84 lb.
Smart Probe	10 oz

Electrical

External Power:	Input: 115-250 VAC, Output: 19 VDC @ 4A
Battery:	Li-Ion battery pack (4 cells)
Leakage Current:	50 µA maximum
Primary Breakdown Voltage:	greater than 1500 V AC
Safety Standards:	IEC 601-1, UL 2601 Can/CSA C22.2 601.1
Protection Class:	Class I: per IEC 601-1
Degree of Protection:	Type BF: per IEC 601-1

Environmental

Mechanical Shock:	EC 68-2-27 compliant (Smart Probe only)
Mechanical Vibration:	Sinusoidal: IEC 68-2-6 (Smart Probe only)
Drop Test (to concrete):	3 feet (Smart Probe only)
Operating Temperature:	0 to 50 C (Smart Probe only)

Humidity:	20 to 80% RH, non-condensing
Water Resistance:	Transducer array watertight to the strain relief
Altitude (Pressure):	63 Kpa to 101.3 Kpa

Storage

Temperature:	-25 to 60°C (Smart Probe only) -40 to 70°C (GETAC CA25)
Humidity:	15 to 98% RH, non-condensing (Smart Probe only)

Refer to computer manufacturer's documentation for relevant environmental specifications.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TERASON™ Model 2000/BAS Portable Ultrasound Systems are substantially equivalent to the products listed in (3.) above, since the subject device has intended uses and modes of operation which are a subset of those of the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2003

TERATECH Corporation
% Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 5112-1891

Re: K030191
Trade Name: Model Terason 2000/BAS Portable Ultrasound System
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: 90 IYN, IYO, and ITX
Dated: January 20, 2003
Received: January 21, 2003

Dear Ms. Danielson:

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 Terason 2000/BAS Portable Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C2
4V2
8L4

8EC4

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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000, BAS Portable Ultrasound Systems
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	P^1N^h	P^2N^h	P^2N^h		P^2N^h	P^2N^h	P^2N^h
	Abdominal:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Intra-operative (Spec.)[e]	N^d	N^d	N^d		N^d	N^d	N^d
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Small Organ (Thyroid, Breast, Testes, etc.):	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Neonatal Cephalic:	P^1	P^2	P^2		P^2	P^2	P^2
	Adult Cephalic	P^1	P^2	P^2		P^2	P^2	P^2
	Trans-rectal	$P^{2,3}N^f$	P^3N^f	P^3N^f		P^3N^f	P^3N^f	P^3N^f
	Trans-vaginal	$P^{2,3}N^g$	P^3N^g	P^3N^g		P^3N^g	P^3N^g	P^3N^g
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Musculo-skel. (Superfic)	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^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:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^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.
[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.
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 K030191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000, BAS Portable Ultrasound Systems
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	P^1N^h	P^2N^h	P^2N^h		P^2N^h	P^2N^h	P^2N^h
	Abdominal	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	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
Includes use 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 A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000, BAS Portable Ultrasound Systems
Transducer: 4V2
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	P^1N^h	P^2N^h	P^2N^h		P^2N^h	P^2N^h	P^2N^h
	Abdominal	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P^1	P^2	P^2		P^2	P^2	P^2
	Adult Cephalic	P^1	P^2	P^2		P^2	P^2	P^2
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent)							
	Musculo-skel. (Superfic)							
	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							
	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.
Includes use 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 K030191

David A. Lyerm

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000/BAS Portable Ultrasound Systems
Transducer: 8L4
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							
	Abdominal:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Intra-operative (Spec.)[e]	N^d	N^d	N^d		N^d	N^d	N^d
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Small Organ (Thyroid, Breast, Testes, etc.):	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Neonatal Cephalic:	P^1	P^2	P^2		P^2	P^2	P^2
	Adult Cephalic	P^1	P^2	P^2		P^2	P^2	P^2
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Musculo-skel. (Superfic)	P^2N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^d
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel:	P^1N^d	P^2N^d	P^2N^d		P^2N^d	P^2N^d	P^2N^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.
[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
Additional Comments: P^1: uses previously cleared under K992505 with 3 MHz Model L3 (Linear);
P^2: uses previously cleared under K012191.
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 A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Terason Model 2000, BAS Portable Ultrasound Systems
Transducer: 8EC4
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	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	$P^{2,3}N^{f}$	$P^{3}N^{f}$	$P^{3}N^{f}$		$P^{3}N^{f}$	$P^{3}N^{f}$	$P^{3}N^{f}$
	Trans-vaginal	$P^{2,3}N^{g}$	$P^{3}N^{g}$	$P^{3}N^{g}$		$P^{3}N^{g}$	$P^{3}N^{g}$	$P^{3}N^{g}$
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	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)
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
Additional Comments: P^{2}: uses previously cleared under K012191;
P^{3}: uses previously cleared under K010883.
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 A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030191