DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TERATECH CORPORATION
C/O MARK JOB
1394 25TH STREET, NW
BUFFALO MN 55313

February 20, 2015

Re: K150148
Trade/Device Name: Terason uSmart3300 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 22, 2015
Received: January 23, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150148

Device Name
Terason uSmart3300 Ultrasound System

Indications for Use *(Describe)*
The Teratech Corporation Terason uSmart3300 is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Ophthalmic, Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-cardiac), Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Trans-esoph. (cardiac) Peripheral Vascular.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 Ultrasound System
Indications For Use: Diagnostic ultrasound imaging system 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	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]	P[2]	P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]	P[2]	P[1]	P[1]	P[1]
	Trans-rectal[f]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-vaginal[g]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N		N	N	N
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]	P[2]	P[1]	P[1]	P[1]
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]	N	P[1]	P[1]	P[1]
	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, thoracic 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 K140773
P[2:] uses previously cleared under K051334

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 9MC3 Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]	N	N	N		N	N	N
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[d]:	N	N	N		N	N	N
	Adult Cephalic[d]:	N	N	N		N	N	N
	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	N		N	N	N	N
	Cardiac Pediatric	N	N		N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	N	N	N	N	N	N	N
	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, thoracic 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.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 8TE3 Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	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.)	N	N	N		N	N	N
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N
	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.
[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, thoracic 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.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – PDOF Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	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			
	Cardiac Pediatric				N			
	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.
[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, thoracic 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.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

_____
(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 15L4 Transducer
Indications For Use: Diagnostic ultrasound imaging system 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	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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, thoracic 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 K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 12L5A Transducer
Indications For Use: Diagnostic ultrasound imaging system 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	N	N	N		N	N	N
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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, thoracic 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 K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 - 4V2A Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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[1]	P[1]	P[1]	P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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.
[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, thoracic 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 K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

_____
(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 5C2A Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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, thoracic 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 K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 – 8EC4A Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-vaginal[g]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	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.
[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, thoracic 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 K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 –8L2 Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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, thoracic 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 K140773

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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 –8V3A Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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[1]	P[1]	P[1]	P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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.
[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, thoracic 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 K140773

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3300 –16HL7 Transducer
Indications For Use: Diagnostic ultrasound imaging system 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]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	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, thoracic 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 K110020

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
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510(k)_____

510(k) Summary

Teratech Corporation

Terason™ uSmart3300 Ultrasound System

1. **Sponsor:**

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa,
Quality Assurance and Regulatory Affairs
Telephone: 781-270-4143

Date Prepared: January 20, 2015

2. **Device Name**

Proprietary Name: Terason™ uSmart3300 Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

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

3. **Predicate Devices**

Terason uSmart3300 Ultrasound System (K140773, K071134), Terason t3000 8MC3 transducer (K112953), Philips iE33 S7-3t TE transducer (K132304, K070792), Aloka ProSound-C3 UST-T109 PDOF transducer (K110482) and Sonosite Edge L25x transducer (K082098).

4. **Device Description**

This system contains a proprietary ultrasound engine for controlling the acoustic output of the transducer and processing the return echoes in real time. These

data are then transferred to the host single-board computer over a FireWire (aka IEEE 1394) connection for further processing and generation and display of the ultrasound image.

The Terason™ uSmart3300 ultrasound weighs approximately 14.6 pounds and has a 15.6” backlit screen. The system dimensions (10”(H) x 14.5”(W) x 2.5”(D)) are chosen to allow the system to be hand carried. A Lithium-Polymer battery (integrated into the unit) provides 2 hours of continuous ultrasound scanning. The system includes a medical-grade power supply (for battery charging). The ultrasound transducer connector is identical to that used in the Terason™ uSmart3300 predicate device. Optional accessories include a cart and printer.

5. Intended Use

The Teratech Corporation Terason™ uSmart3300 is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Ophthalmic, Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-cardiac), Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Trans-esoph. (cardiac) Peripheral Vascular.

6. Technology Characteristics

The design and construction of the Terason™ uSmart3300 ultrasound system is identical to the Terason™ uSmart3300 predicate system. This system utilizes a single-board computer running Windows 7 to execute the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. For the uSmart3300, the engine is housed in a compartment that is attached to the base of the chassis.

The similarities and differences between the Terason™ uSmart3300 (current filing) and the predicate Terason uSmart3300 Ultrasound System (K140773) include the following:

- The engines are the identical with no modifications. As in the predicate device, the custom beamformer chip provides the processing of the return ultrasound echoes to support wide bandwidth signals and provide enhanced resolution across the entire image field.

- The ultrasound application software has been modified to support 3 new transducers (9MC3, 8TE3, PDOF) and the new Ophthalmic indication for use (with the 15L4 and 12L5A transducers). The predicate devices that provide identical Ophthalmic indications for use are: K071134 (system) and K082098 (transducer).

Transducers: The Terason uSmart3300 will support 3 new transducers and the new Ophthalmic indication for use (IFU). (The Terason uSmart3300 has been previously cleared with eight transducers in K140773). The new transducers and associated predicate devices include:

- 9MC3: Predicate device 8MC3 cleared in 510k submission K112953
- 8TE3: Predicate device Philips(Oldelft) S7-3t previously cleared in 510k submissions K132304 and K070792
- PDOF: Predicate device Aloka ProSound-C3 UST-T109 previously clear in 510k submission K110482
- 15L4: Ophthalmic IFU predicate device Sonosite Edge L25x previously cleared in 510k submission K082098
- 12L5A: Ophthalmic IFU predicate device Sonosite Edge L25x previously cleared in 510k submission K082098.

The following provides additional details of the 5 transducers presented in this submission.

- 9MC3: Identical indications for use to the predicate transducer 8MC3. Different frequency range but the shape of the transducer is identical when compared to the predicate. Same manufacturer, same acoustic array and patient contact materials as the predicate 8MC3 transducer.
- 8TE3: Identical indications for use to the predicate trans-esophageal (TE) probe Philips(Oldelft) S7-3t. Similar frequency range and probe shape when compared to the predicate. Same original manufacturer (Oldelft), same acoustic array and patient contact materials as the predicate Philips S7-3t TE probe.
- PDOF: Identical indications for use to the predicate PDOF Aloka ProSound-C3 UST-T109 transducer. Identical frequency range and probe shape when compared to the predicate. Same original manufacturer (Sound Technology), same acoustic array and patient contact materials as the predicate Aloka UST-T109 transducer.
- 15L4: Similar Ophthalmic indication for use, frequency settings, and shape of transducer head as the predicate Sonosite Edge L25x transducer. Different manufacturer (Vermon). Similar acoustic array and patient contact materials.
- 12L5A: Similar Ophthalmic indication for use, frequency settings, and shape of transducer head as the predicate Sonosite Edge L25x transducer. Different manufacturer (Apex). Similar acoustic array and patient contact materials.

7. Table of Similarities and Differences Compared to the Predicate Devices

New Transducers: 9MC3, 8TE3, PDOF
New Indication for Use (IFU): Ophthamology for 15L4 and 12L5A transducers
Previously Cleared Transducers (K140773): 8EC4A, 16HL7, and 15L4, 12L5A, 5C2A, 4V2A, 8V3A, and 8L2

Terason uSmart3300 Ultrasound System

	Subject Device Model **Terason uSmart3300** **(This Submission)**	**Comparable Predicate Device** **Terason uSmart3300** **K140773**	**Comparable Predicate Device** **Sonosite Maxx** **K071134**
Intended Use	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body
Indication for Use	Ophthalmic, Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-Cardiac and Cardiac), Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric), Peripheral Vascular	Fetal, Abdominal, Intra-operative (Spec. and Neuro.), Pediatrics, Small Organ (Thyroid, Breast, Testes), Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional and Superficial), Cardiac (Adult and Pediatric), Peripheral Vascular	Ophthalmic, Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro), Laparoscopic, Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superficial), Cardiac Adult, Cardiac Pediatric,Trans-esophageal (Cardiac), Peripheral vessel
Transducer Types	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear PDOF Trans-esophageal	Linear Array Curved Array Phased Array Endocavity – curved array	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Transesophageal
Acoustic Output and FDA Limits	Display Features for High Outputs	Display Features for High Outputs	Display Features for High Outputs
Global Maximum Outputs/Worst Case Setting	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIB (4V2A) TI Value: 5.64 (4V2A)	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIB (4V2A) TI Value: 5.64 (4V2A)	N/A

	MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 1029 W/cm^2 (15L4)	MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 1029 W/cm^2 (15L4)	
Modes of Operation	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler
PW Doppler	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF
Transducer Frequency	2.0 – 15.0 MHz	2.0 – 15.0 MHz	2.0 – 15.0 MHz (est.)
#Transmit Channels	128 Channels	128 Channels	128 Channels
# Receive Channels	128 Channels	128 Channels	128 Channels
Acoustic Output Measurement Standard	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004
DICOM	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM supported
Product Safety Certification	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-4 IEC60601-2-37
EMC	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B
System Characteristics	**uSmart3300:** Integrated single-board computer Weighs 14.6 lbs (6.62 Kg) 15.6” backlit touch screen. System dimensions (15.58”(H) x 15.29”(W) x 3.5”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning Medical-grade power supply Data transferred to the single-board computer over a FireWire (aka IEEE 1394)	**uSmart3300:** Integrated single-board computer Weighs 14.6 lbs (6.62 Kg) 15.6” backlit touch screen. System dimensions (15.58”(H) x 15.29”(W) x 3.5”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning Medical-grade power supply Data transferred to the single-board computer over a FireWire (aka IEEE 1394)	**Sonosite Maxx:** Information available on the corporate web site: http://www.sonosite.com.

Three transducers have been added to the Terason uSmart3300 in this submission: 9MC3, 8TE3 and PDOF. A new indication for use (IFU) that is included in this submission is for Ophthalmic use with the 15L4 transducer.

9MC3 Transducer

Key Features	**Subject Device Model** **Terason 9MC3 Transducer**	**Comparable Predicate Device** **Terason 8MC3 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K112953	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) to image fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels.	The transducer is intended to be used with a conventional ultrasound system (Terason t3000) to image fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: **Same.** **Effectiveness**: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Micro Curved Array	Micro Curved Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 80 6.5 0.321mm X 6.0mm 30mm	 128 5.0 0.25mm X 8.0mm 40mm	**Different:** Element count, center frequency, element size and elevation focus. Acoustic characteristics have met safety guidelines of IEC60601-2-37. Safety and effectiveness unchanged from predicate.
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K112953).	**Same:** The 9MC3 uses a same acoustic array materials as the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone ABS	Silicone ABS	**Same**: The contact material is identical.

Discussion:
The 9MC3 uses a same acoustic array materials as the predicate (8MC3) device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 9MC3 consists of same patient contact material as the predicate device. To ensure proper safety guidelines are met, biocompatibility tests were run on the patient contact materials.

Transducer 8TE3

Key Features	**Subject Device Model** **Terason(Oldelft) 8TE3 Transducer**	**Comparable Predicate Device** **Philips(Oldelft) S7-3t**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K132304 (EPIQ) K070792 (iE33)	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) for trans-esophageal (non-cardiac and cardiac) imaging.	The transducer is intended to be used with a conventional ultrasound system (Philips EPIQ) for trans-esophageal (non-cardiac and cardiac) imaging.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology	Piezoelectric elements	Piezoelectric elements	**Same**
Transducer Style	TE (Trans-esophageal)	TE (Trans-esophageal)	**Same.**
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	64 5.0 MHz 0.16mm X 9.6mm 50mm	64 5.0 MHz 0.16mm X 9.6mm 50mm	**Same.**
Acoustic Output and Device Settings	The transducer performance has been evaluated in an acoustic tank	The transducer performance has been evaluated in the previous 510(k) filing (K132304, K070792).	**Same.**
Patient Contact Material	Silicone	Silicone	**Same.** The 8TE3 and the predicate S7-3t transducers are both manufactured by Oldelft and consist of identical patient contact materials.

Discussion:

There are no differences between this device and the predicate device used in this comparison. The transducer has been added to the uSmart3300 Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 8TE3 transducer is substantially equivalent to the predicate TE transducer with respect to safety and effectiveness.

PDOF Transducer

Key Features	**Subject Device Model** **Terason uSmart3300 PDOF Transducer**	**Comparable Predicate Device** **Aloka(Terason) ProSound C3 UST-T109 PDOF Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K110482	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) for Cardiac continuous-wave Doppler (CWD) (adult and pediatric).	The transducer is intended to be used with a conventional ultrasound system (Aloka/Terason ProSound C3) for Cardiac continuous-wave Doppler (CWD) (adult and pediatric).	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Pencil Transducer	Pencil Transducer	
Acoustic Array Characteristics: **Element count…** **Center frequency** **Element size (diameter)…** **Elevation focus…**	 2 2.0MHz 13.8mm 55mm	 2 2.0MHz 13.8mm 55mm	**Same.**

Acoustic Array	The transducer CWD performance has been evaluated in an acoustic tank.	The transducer CWD performance has been evaluated in the previous 510(k) filing ().	**Same.** As the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Epoxy Noryl	Epoxy Noryl	**Same.** The PDOF transducer consists of identical patient contact materials as the predicate device.

Discussion:

There are no differences between this device and the predicate device used in this comparison. The transducer has been added to the uSmart3300 Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason PDOF transducer is substantially equivalent to the predicate PDOF transducer with respect to safety and effectiveness.

15L4 Transducer

Key Features	**Subject Device Model** **Terason 15L4 Transducer**	**Comparable Predicate Device** **Sonosite Edge L25x/13-6 Transducer**	**Same or Different**
510(k) Number	K1XXXXX	K082098	n/a
Classification	ITX	ITX	**Same**
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3300) to image ophthalmic, abdomen, small parts, musculo-skel, peripheral vascular regions. Ophthalmic is the new IFU.	The transducer is intended to be used with a conventional ultrasound system (Sonosite Edge) to image ophthalmic, abdomen, pediatric, small parts, musculo-skel and peripheral vascular regions.	**Different:** The proposed transducer and the predicate transducer have the claim of imaging similar regions in the human body. Ophthalmic is the new Indication for Use.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same:** Identical material.

Acoustic Array Style:	Linear Array	Linear Array	**Effectiveness:** Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 128 elements 7.5 MHz 0.3mm X 4.0mm 20mm	 128 elements 9.5 MHz (est) 0.195mm X 3.0mm (est) 18mm (est)	**Same:** element count. Acoustic characteristics have met safety guidelines of IEC60601-2-37.
Acoustic Output and Device Settings	The transducer performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the 510(k) filing (K082098).	**Different;** acoustic output safety guidelines. Safety is not compromised. Effectiveness equal.
Patient Contact Material	Silicone ABS	Silicone ABS	**Same.** The 15L4 transducer consists of same patient contact materials as the predicate device. The safety of each device with respect to biocompatibility is equivalent.

Discussion:

The 15L4 uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines for ophthalmic use are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 15L4 transducer consists of same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15L4 transducer is substantially equivalent to the Sonosite L25x transducer (K082098) with respect to safety and effectiveness. Based on test results, the 15L4 transducer can be safely used for ophthalmological use.

12L5A Transducer

Key Features	Subject Device Model Terason 12L5A Transducer	Comparable Predicate Device Sonosite Edge L25x/13-6 Transducer	Same or Different
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K082098	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image ophthalmic, fetal, abdominal, pediatric, small organ, cephalic, musculo-skel, cardiac and peripheral vessel. Ophthalmic is the new IFU.	The transducer is intended to be used with a conventional ultrasound system (Sonosite Edge) to image ophthalmic, abdomen, pediatric, small parts, musculo-skel and peripheral vascular regions.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Linear Array	Linear Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 128 7.5MHz 0.3mm X 4.0mm 19mm	 128 9.5MHz (est) 0.195mm X 3.0mm (est) 18mm (est)	**Same in elevation** Safety and effectiveness unchanged from predicate
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K082098).	**Same.** As the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.

Patient Contact Material	Silicone ABS	Silicone ABS	**Same.** The 12L5A transducer consists of same patient contact materials as the predicate device.

Discussion:
The 12L5A uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines for ophthalmic use are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 12L5A transducer consists of same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 12L5A transducer is substantially equivalent to the Sonosite L25x transducer (K082098) with respect to safety and effectiveness. Based on test results, the 12L5A transducer can be safely used for ophthalmological use.

Previously filed transducers:

The following transducers are identical to those previously cleared under FDA 510(k) K140773, May 30, 2014 for the Terason uSmart3300:

- 4V2
- 5C2A
- 8EC4A
- 8L2
- 8V3A
- 12L5A (not including Ophthalmic use)
- 15L4 (not include Ophthalmic use)
- 16HL7.

3. Accessories / Kits:

There are no new accessories associated with the new transducers or ophthalmic indications for use.

Accessories previously cleared under FDA 510(k) K140773 include:

uSmart3300 Transducer	Starter Contents	FDA 510k Clearance #	Replacement Kit	FDA 510k Clearance Numbers
5C2A	Protek kit #7138	K973958	Protek 16 Ga biopsy kit #4216 Protek 18 Ga biopsy kits #4218 Protek 22 Ga biopsy kits #4222 Biopsy kits include needle guide, probe cover, and gel	K140773 K973958
15L4	Civco 612-085 (inplane) needle guide Starter Kit Civco 683-002 (transverse) needle guide starter kit	K882383/A	Civco 610-579	K140773 K882383/A

4) Conclusion

The intended uses and features are consistent with the traditional clinical practices and FDA guidance for clearance of Diagnostic ultrasound systems and transducers. The uSmart3300 and predicate devices both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3300 and predicate devices both meet FDA requirements for track 3 devices, indications for use, biocompatibility, and are manufactured using FDA GMPs and ISO-13485 quality systems. Teratech Corporation believes that the uSmart3300 ultrasound system is substantially equivalent with regards to safety and effectiveness to the predicate devices as noted above.

B1. Non Clinical Tests

The Terason™ uSmart3300 system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Basic Safety.
    - Intertek Test Record Number 101288219BOX-004.

- IEC60950-1 Information Technology Equipment – Safety – Part 1: General Requirements
    - IEC60950-1 IEI Integration Corp. Test Report Number, 1308046001.

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
    - IEC60601-2-37 Transducer Model 8TE3 [Intertek Report 101501543BOX-006]
    - IEC60601-2-37 Transducer Model 12L5A Ophthalmic [Intertek Report 100404853BOX-006]
    - IEC60601-2-37 Transducer Model 15L4 Ophthalmic [Intertek Report 100404853BOX-007]
    - IEC60601-2-37 Transducer Model 9MC3 [Intertek Report #100404854BOX-001b]
    - IEC60601-2-37 Transducer Model PDOF [Intertek Report #100404858BOX-002].

IEC 60601-2-37 reports associated with previously cleared transducers can be found in FDA 510(k) K140773.

- IEC60601-1-2:2007 / EN60601-1-2:2007 Electromagnetic Compatibility, Harmonic Current Emissions
    - IEC60601-1-2:2007 8TE3 Transducer [Oldelft Technical Report 2011-002]
    - IEC60601-1-2:2007 EMC Emissions Evaluation of Terason uSmart3300 Cart with 3 port MUX [Intertek Report #101753715BOX-001]

IEC 60601-1-2:2007 reports associated with previously the cleared Terason uSmart3300 ultrasound system can be found in FDA 510(k) K140773.

- NEMA UD 3 Acoustic Output Display
  Terason uSmart3300 Ultrasound System User Guide, Volume 2 (16-3312).

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
    - Biocompatibility reports for all transducers.