Teratech Corporation
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

July 2, 2020

Re: K201633
Trade/Device Name: Terason™ uSmart 3200T Plus Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: June 12, 2020
Received: June 16, 2020

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201633

Device Name
Terason uSmart3200T Plus Ultrasound System

Indications for Use *(Describe)*
The Teratech Corporation Terason uSmart3200T Plus is a prescription-only, general-purpose Ultrasound System intended for use by a qualified physician or accredited sonographer for evaluation by ultrasound imaging or fluid-flow analysis of the human body. The device is intended for use in a clinic, hospital or medical-emergency setting. 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-esophageal (non-cardiac), Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric), Trans-esophageal (cardiac), and 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
Food and Drug Administration
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."

510(k) Summary

K201633

Teratech Corporation

Terason uSmart3200T Plus Ultrasound System

1. **Sponsor:**

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

Contact Person: Ben Chiampa
Director of Quality Assurance
Telephone: 781-270-4143

Date Prepared: May 20, 2020

2. **Device Name**

Proprietary Name: Terason uSmart3200T Plus Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Class II

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 Device**

Terason™ uSmart3200T Ultrasound System (K193510)

4. **Intended Use**

The Teratech Corporation Terason™ uSmart3200T Plus is a prescription-only, general-purpose Ultrasound System intended for use by a qualified physician or accredited sonographer for evaluation by ultrasound imaging or fluid flow

analysis of the human body. The device is intended for use in a clinic, hospital or medical-emergency setting. 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-esophageal (non-cardiac), Musculo-skeletal (Conventional and Superficial), Cardiac (Adult & Pediatric), Trans-esophageal (cardiac), and Peripheral Vascular.

5. Clinical Testing

Teratech Corporation certifies that the requirements of 42 U.S.C. 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this 510(k) filing accompanies does not reference any clinical trial.

6. Device Description

The Terason uSmart3200T Plus ultrasound system is a portable tablet-style, full-feature, general purpose diagnostic ultrasound system used to acquire and display high–resolution, real-time ultrasound data through multiple imaging modes. The Terason uSmart3200T Plus Ultrasound System is equivalent to the previously cleared versions of the uSmart3200T Ultrasound Systems. The modification includes the addition of 3 transducers: 14L3, 10BP4 and 15XL4.

The Terason™ uSmart3200T ultrasound system was the previously cleared on the date January 29, 2020 as described in the 510(k) submission (K193510). 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 tablet computer over a Universal Serial Bus (USB3) connection for further processing and generation/display of the ultrasound image.

The Terason™ uSmart3200T Plus ultrasound tablet weighs 9.8 pounds (4.2 Kg) and has an 15.6” backlit touch screen. The tablet dimensions (10.6”(H) x 15.6”(W) x 1.7”(D)) are chosen to allow portability. A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning. The tablet includes a docking station (for charging) that uses a medical-grade power supply. The ultrasound transducer connector is identical to that used in the

Terason™ predicate device, the uSmart3200T Plus. Optional accessories include a cart and printer.

7. Technology Characteristics

The design and construction of the Terason uSmart3200T Plus is the same as the Terason uSmart3200T Plus Ultrasound system which was cleared in May 2015. This system utilizes a portable computer running Windows 10 to run the ultrasound application and a custom hardware designed engine for control of the acoustic array and processing of the return echoes. The engine is housed in a compartment that is inside the tablet.

The uSmart3200T Plus system contains the same ultrasound engine as the predicate device Terason uSmart3200T Plus ultrasound system for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the tablet computer over a USB3 connection for further processing, and generation and display of the ultrasound image

The differences between the Terason uSmart3200T Plus and the previous Terason uSmart3200T Plus Ultrasound System (the predicate device) include the following:

- Three transducers have been added to the system: 14L3, 10BP4, and 15XL4. The software has been modified to control these transducers and ensure compliance to the standards controlling acoustic and thermal power.
- Added support for the 14L3, 10BP4, and 15XL4 transducers
    - Confirmed transducer id numbers and names
    - Confirmed transducer geometries and characteristic parameters
    - Confirmed 14L3, 10BP4, and 15XL4 acoustic tables
    - Added 14L3, 10BP4, and 15XL4 to the table of allowed transducers
    - Added imaging presets for 14L3, 10BP4, and 15XL4 transducers.

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

Terason uSmart3200T Plus System and Transducers Comparison and Discussion
New Transducers: 14L3, 10BP4, 15XL4
Previously cleared transducers (5V1A, 12L5A, 5C2A, 8EC4A, 16HL7, 15L4, 8L2, 8V3A, 9MC3, 8TE3, PDOF, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4) (K193510)

Terason uSmart3200T Plus Tablet Computer

	Subject Device Model Terason uSmart3200T Plus (This Submission)	**Comparable Predicate Device Terason uSmart3200T K193510**	**Same or Different**
Intended Use	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Same.
Indication for Use	Ophthalmic, Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-Cardiac), Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel	Ophthalmic, Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal (non-Cardiac), Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel	Same.
Transducer Types	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Trans-esophageal PDOF 192-Element 384-element XY-Biplane Endocavity-Biplane	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Trans-esophageal PDOF 192-Element XY-Biplane	Different: Support for 384-elements and biplane transducers.
Acoustic Output and FDA Limits	Display Features for High Outputs	Display Features for High Outputs	Same.
Global Maximum Outputs/Worst Case Setting	$I_{SPTA.3}$: 619 mW/cm^2 (10BP4C) TI Type: TIC (14L3) TI Value: 4.2 (14L3) MI: 1.76 (15XL4) $I_{PA.3}$@MI Max: 776 W/cm^2 (14L3)	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIC (15L4) TI Value: 5.8 (15L4) MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 827 W/cm^2 (15L4)	Different. Within Guideline limits.

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	Same.
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	Same.
Transducer Frequency	2.0 – 15.0 MHz	2.0 – 15.0 MHz	Same.
#Transmit Channels	384 Channels	128 Channels	Different. Supports 384 elements.
# Receive Channels	384 Channels	128 Channels	Different. Supports 384 elements.
Acoustic Output Measurement Standard	IEC 60601-2-37	NEMA UD 2-2004 NEMA UD 3-2004	Same.
DICOM	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	Same.
Product Safety Certification	AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for safety and essential performance IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for safety and essential performance IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	Same.
EMC	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B	Same.
System Characteristics	**uSmart3200T Plus:** tablet computer weighs 9.8 lbs (4.2 Kg) 18” backlit touch screen. Tablet dimensions (10.6”(H) x 15.6”(W) x 1.7”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of	**uSmart3200T:** tablet computer weighs 4.9 lbs (2.21 Kg) 11.5” backlit touch screen. Tablet dimensions (8.82”(H) x 12.64”(W) x 1.25”(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of	Different. Larger screen

	continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply Data transferred to the tablet computer over a USB3 connection	continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply Data transferred to the tablet computer over a USB3 connection	

Three transducers have been added to the Terason uSmart3200T Plus in this submission: 14L3, 10BP4, and 15XL4.

SUMMARY OF NEW AND ASSOCIATED PREDICATE TRANSDUCERS

New Subject Transducer	Comparable Predicate Transducer	Predicate Approvals and Systems
Terason 14L3	Terason 15L4	K193510 (Terason uSmart3200T)
Terason 10BP4	Terason 10EC4	K193510 (Terason uSmart3200T)
Terason 15XL4	Terason 15WL4	K193510 (Terason uSmart3200T)

TRANSDUCER PERFORMANCE SUMMARY

Transducer	Indications	Mode	Global maximum output	510(K) control number
12L5A	Ophthalmic, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Neonatal and Adult Cephalic, Musculo-sketetal (Conventional and Superficial), and Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 597(mW/cm^2) TI = 3.3 MI = 1.8	K193510
5V1A	Fetal, Abdominal, Pediatric, Neonatal and Adult Cephalic, Cardiac (adult and pediatric)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 603 (mW/cm^2) TI = 5.6 MI = 1.5	K193510
5C2A	Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes, etc.); Musculo-sketetal (Conventional and Superficial), Cardiac (adult and pediatric) and Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 660 (mW/cm^2) TI = 4.7 MI = 0.7	K193510
8EC4A	Fetal, Trans-rectal, Trans-vaginal	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 633(mW/cm^2) TI = 2.29 MI = 1.8	K193510
16HL7	Intra-Operative (abdominal, organs and vascular), Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular.	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 554(mW/cm^2) TI = 1.22 MI = 1.6	K193510
15L4	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular.	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 563(mW/cm^2) TI = 5.8 MI = 1.7	K193510
8L2	Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 598(mW/cm^2) TI = 2.8 MI = 1.7	K193510
8V3A	Fetal, Abdominal, Pediatric, Cephalic, and Cardiac	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 560(mW/cm^2) TI = 4.7 MI = 1.7	K193510
9MC3	fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels	B, M, PWD, Color Doppler, CWD,	$I_{STPA.3}$ = 577(mW/cm^2) TI = 2.8 MI = 1.3	K193510

		Combined		
8TE3	Trans-esophageal (non-cardiac and cardiac)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 245(mW/cm^2) TI = 1.0 MI = 1.3	K193510
PDOF	Cardiac	CWD	$I_{STPA.3}$ = 506(mW/cm^2) TI = 4.2 MI = 0.1	K193510
15L4A	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 620 (mW/cm^2) TI = 1.8 MI = 1.7	K193510
16L5	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 635 (mW/cm^2) TI = 1.6 MI = 1.7	K193510
15WL4	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 624 (mW/cm^2) TI = 3.3 MI = 1.8	K193510
XY-Biplane	Fetal, Abdominal, Pediatric, Neonatal and Adult Cephalic, Cardiac (adult and pediatric)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 650 (mW/cm^2) TI = 5.7 MI = 1.7	K193510
10EC4	Fetal, Trans-rectal, Trans-vaginal	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 616 (mW/cm^2) TI = 2.56 MI = 1.56	K193510
14L3	Ophthalmic, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular.	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 618 (mW/cm^2) TI = 4.2 MI = 1.75	New
10BP4	Fetal, Trans-rectal, Trans-vaginal	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 606 (mW/cm^2) TI = 0.99 MI = 1.75	New
15XL4	Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes); Musculo-skeletal (Conventional and Superficial); Peripheral Vascular	B, M, PWD, Color Doppler, Combined	$I_{STPA.3}$ = 620 (mW/cm^2) TI = 3.3 MI = 1.8	New

14L3 Transducer

Key Features	**Subject Device Model** **Terason uSmart3200T Plus 14L3 Transducer**	**Comparable Predicate Device** **Terason 15L4 Transducer**	**Same or Different**
Device Classification	Class II	Class II	**Same**
510(k) Number	KXXXXX	K193510	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T Plus) to image ophthalmic, abdomen, small parts, musculo-skel, peripheral vascular regions.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image ophthalmic, abdomen, small parts, musculo-skel, 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 Transducer	Linear Transducer	
Acoustic Array Characteristics: **Element count…** **Center frequency** **Element size (diameter)…** **Elevation focus…**	 128 5 MHz 0.3mm X 4.5mm 20mm	 128 7.5 MHz 0.3mm X 4mm 16mm	**Different.** The new transducer has the same number of elements operating a lower frequency for deeper imaging.
Acoustic Array	The transducer performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filings (K193510).	**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 (proprietary)	Silicone R1001	**Different.** The 14L3 has passed cytotoxicity, sensitization, and irritation biocompatibility tests.

Discussion:

There 14L3 has the same number of elements operating at a lower frequency than the predicate device used in this comparison. The transducer has been added to the uSmart3200T Plus Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 14L3 transducer is substantially equivalent to the predicate 15L4 transducer with respect to safety and effectiveness.

15XL4 Transducer

Key Features	**Subject Device Model** **Terason 15XL4 Transducer**	**Comparable Predicate Device** **Terason 15WL4 Transducer**	**Same or Different**
Device Classification	Class II	Class II	**Same**
510(k) Number	K1XXXXX	K193510	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T Plus) to image Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular.	**Same.**
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** **Same.** Regarding Safety: This array allows 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…**	 384 6.3 MHz 0.286mm X 4mm 20mm	 192 6.3 MHz 0.286mm X 4mm 16mm	**Different.** Additional 192 elements operating at the same frequency.
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 (K193510).	**Same.** As the predicate device and therefore has the same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	SIM R1001	SIM R1001	**Same.**

The 15XL4 has an additional 192 elements that operate at the same frequency as the predicate device. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The 15XL4 transducer used with the uSmart3200T Plus consists of the same patient contact materials as the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15XL4 transducer meets safety and effectiveness guidelines.

_____

10BP4 Transducer

Key Features	**Subject Device Model** **Terason 10BP4 Transducer**	**Comparable Predicate Devices** **Terason 10EC4 Transducer** **Terason 15L4 Transducer**	**Same or Different**
Device Classification	Class II	Class II	**Same**
510(k) Number	K1XXXXX	K193510	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T Plus) to image Fetal, Trans-rectal, Trans-vaginal.	The 10EC4 transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Trans-rectal, Trans-vaginal.	**Same.** Indications for Use.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Elements and shape are the same.
Acoustic Array Style:	Linear and Micro-convex	Micro-convex (10EC4) Linear (15L4)	
Manufacturer:	Vermon	Vermon	**Same:** Same manufacturer.
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **ROC** **Elevation focus…**	 192 Curved and Linear 7.0 MHz 0.18mm X 4.2mm Curved 0.37mm X 5mm Linear 10 mm 20mm	 192 (10EC4) and 128 (15L4) 7.2 MHz (10EC4) 7.5 MHz (15L4) 0.205mm X 5mm (10EC4) 0.3mm X 4mm (15L4), 8.8 mm (10EC4) 35 mm (10EC4), 16mm (15L4)	**Different.** The new 10BP4 provides a slightly lower frequency response. The 192 elements have similar pitch and elevation apertures compared to the predicates.
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 (K193510).	**Same.** To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	SIM R1002 (Silicone)	15L4 transducer SIM R1002	**Same.** The Silicone lens is identical to the previously cleared (K193510) 15L4 transducer lens material.

The 10BP4 transducer is manufactured by Vermon that also makes other Terason transducers. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The 10BP4 transducer used with the uSmart3200T Plus consists of different contact materials when compared with the predicate device.

Based on the test results, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 10BP4 transducer meets safety and effectiveness guidelines.

Previously filed transducers:

The following transducers are identical to those previously cleared under FDA 510(k) K193510, May 9, 2015 for the Terason uSmart3200T:

- 4V2
- 5C2A
- 8EC4A
- 12L5A
- 15L4
- 16HL7
- 8L2
- 8TE3
- 8V3A
- 9MC3
- PDOF
- 15L4A
- 16L5
- 15WL4
- XY-Biplane
- 10EC4.

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 uSmart3200T Plus and predicate device both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3200T Plus and predicate device both meet FDA requirements for Track 3 devices, indications for use, biocompatibility similarities, and are manufactured using FDA GMPs and ISO-13485 quality systems. Teratech Corporation believes that the uSmart3200T Plus ultrasound system is substantially equivalent with regards to safety and effectiveness to the predicate device.

9. Summary of Bench Tests and Non-Clinical Tests

The Terason uSmart3200T Plus system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for safety and essential performance
- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests

- EMC Test Report for the Terason uSmart3200T Plus

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

- Biocompatibility Tests, ISO 10993 Part 5, Part 10 and Part 12
    - Biocompatibility reports for the new transducers
- AAMI TIR No. 12:210, Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

The ultrasound system acoustic output was tested in accordance with the following:

- IEC 61157, Ed. 2 2007-2008, Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3
- NEMA UD 3, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2.

The ultrasound system B-Mode Accuracy, Doppler Accuracy and Doppler Sensitivity for each Terason transducer have been evaluated according to the following:

- American Institute of Ultrasound in Medicine (AIUM) Quality Assurance Manual for Gray-Scale Ultrasound Scanners
- AIUM Methods for Measuring Performance of Pulse-Echo Ultrasound Imaging Equipment, Part II: Digital Methods
- AIUM Performance Criteria and Measurements for Doppler Ultrasound Devices.

The Terason uSmart3200T Plus Software has undergone Quality Assurance testing consistent with IEC 62304, Software Life Cycle Process, and IEC 62366, Application for Usability.

The performance data used to validate the Terason uSmart3200T Plus and new transducers includes the following:

- Acoustic output testing
- B-Mode accuracy, and Doppler accuracy and sensitivity
- General requirements for safety testing
- Electromagnetic compatibility testing
- Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment testing
- Biocompatibility testing of patient contact materials
- Burn-in testing
- Software performance and regression testing.

10. Summary of Conclusions

The predicate system (uSmart3200T, K193510) and associated predicate transducers are legally marketed. The new system and associated transducers have the same intended use as the predicate system and devices. The Terason uSmart3200T Plus and associated transducers represent an improved implementation of familiar technology and therefore possess new technological characteristics that are validated in this filing.