Teratech Corporation
% Mr. Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

January 28, 2020

Re: K193510
Trade/Device Name: Terason uSmart3200T 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: January 17, 2020
Received: January 21, 2020

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. 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 P R A Statement on last page.

510(k) Number: K193510

Device Name
Terason uSmart3200T Ultrasound System

Indications for Use *(Describe)*

The Teratech Corporation Terason™ uSmart3200T 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.

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510(k) Summary

K193510

Teratech Corporation

Terason uSmart3200T 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: August 15, 2018
Revised: January 6, 2020

2. **Device Name**

Proprietary Name: Terason uSmart3200T 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 Device**

Terason™ uSmart3200T Ultrasound System (K150533)

Supporting Predicate Devices:
Terason™ 4V2A Transducer (K150533)
Terason™ 12L5A Transducer (K150533)
Terason™ 15L4 Transducer (K150533)
Terason™ 8EC4A Transducer (K150533)

4. Intended Use

The Teratech Corporation Terason™ uSmart3200T 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. Device Description

The Terason uSmart3200T 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 Ultrasound System is equivalent to the previously cleared versions of the uSmart3200T Ultrasound Systems. The modification includes the addition of 6 transducers (5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4), the Ophthalmic IFU associated with the 15L4A transducer with no change to the tablet-style computer form factor.

The Terason™ uSmart3200T ultrasound system was the previously cleared on the date May 9, 2015 as described in the 510(k) submission (K150533). 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 ultrasound tablet weighs 4.9 pounds (2.21 Kg) and has an 11.5” backlit touch screen. The tablet dimensions (8.82”(H) x 12.64”(W) x 1.25”(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. Optional accessories include a cart and printer.

6. Technology Characteristics

The design and construction of the Terason uSmart3200T is the same as the Terason uSmart3200T 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 system contains the same ultrasound engine as the predicate device Terason uSmart3200T 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 and the previous Terason uSmart3200T Ultrasound System (the predicate device) include the following:

- Six transducers have been added to the system. The new Ophthalmic Indication for Use is associated with the 15L4A transducer. The software has been modified to control these transducers and ensure compliance to the standards controlling acoustic and thermal power.
- Added support for the 5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4 transducers
    - Confirmed transducer id numbers and names
    - Confirmed transducer geometries and characteristic parameters
    - Confirmed 5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4 and ophthalmic-15L4A acoustic tables
    - Added 5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4 to the table of allowed transducers
    - Added imaging presets for 5V1A, 15L4A, 16L5, 15WL4A, XY-Biplane, 10EC4 transducers. Added presets for the new 15L4A ophthalmic mode.

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

Terason uSmart3200T System and Transducers Comparison and Discussion
New Transducers 5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4 and for Ophthalmic Indication for Use 15L4A
Previously cleared transducers (12L5A, 5C2A, 4V2A, 8EC4A, 16HL7, 15L4, 8L2, 8TE3, 8V3A, 9MC3) (K150533)

Terason uSmart3200T Tablet Computer

	Subject Device Model Terason uSmart3200T (This Submission)	**Comparable Predicate Device Terason uSmart3200T K150533**	**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 XY-Biplane	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Trans-esophageal PDOF	Different: Support for 192-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	$I_{SPTA.3}$: 660 mW/cm^2 (5C2A) TI Type: TIC (15L4) TI Value: 5.8 (15L4) MI: 1.8 (Various) $I_{PA.3}$@MI Max: 829 W/cm^2 (15L4)	$I_{SPTA.3}$: 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	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion) Anatomical M-Mode Color M-Mode	Same.

	Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	
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	192 Channels	128 Channels	Different. Supports 192 elements.
# Receive Channels	192 Channels	128 Channels	Different. Supports 192 elements.
Acoustic Output Measurement Standard	NEMA UD 2-2004 NEMA UD 3-2004	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:** 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 continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply	**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 continuous ultrasound scanning Docking station (for charging) that uses a medical-grade power supply	Different. USB3 instead of IEEE 1394

	Data transferred to the tablet computer over a USB3 connection	Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	

Six transducers have been added to the Terason uSmart3200T in this submission: 5V1A, 15L4A, 16L5, 15WL4, XY-Biplane, 10EC4. The new indications for use (IFU) that are included in this submission are for Ophthalmic use with the high-frequency transducers.

SUMMARY OF NEW AND ASSOCIATED PREDICATE TRANSDUCERS

New Subject Transducer	Comparable Predicate Transducer	Predicate Approvals and Systems
Terason 5V1A	Terason 4V2A	K150533 (Terason uSmart3200T)
Terason 15L4A	Terason 12L5A	K150533 (Terason uSmart3200T)
Terason 16L5	Terason 15L4	K150533 (Terason uSmart3200T)
Terason 15WL4	Terason 15L4	K150533 (Terason uSmart3200T)
Terason XY-Biplane	Terason 15L4	K150533 (Terason uSmart3200T)
Terason 10EC4	Terason 8EC4A	K150533 (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	K150533
4V2A	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	K150533
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	K150533
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	K150533
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	K150533
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	K150533
8L2	Abdominal, Pediatric, Musculo-	B, M,	$I_{STPA.3}$ = 598(mW/cm^2)	K150533

	skeletal, Peripheral Vascular	PWD, Color Doppler, Combined	TI = 2.8 MI = 1.7	
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	K150533
9MC3	fetal, pediatric, small organs, cephalic (neonatal and adult), cardiac and peripheral vessels	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 577(mW/cm^2) TI = 2.8 MI = 1.3	K150533
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	K150533
PDOF	Cardiac	CWD	$I_{STPA.3}$ = 506(mW/cm^2) TI = 4.2 MI = 0.1	K150533
5V1A	Fetal, Abdominal, Pediatric, Neonatal and Adult Cephalic, Cardiac (adult and pediatric)	B, M, PWD, Color Doppler, CWD, Combined	$I_{STPA.3}$ = 653 (mW/cm^2) TI = 5.6 MI = 1.7	New
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	New
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	New
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	New
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	New
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	New

5V1A Transducer

Key Features	**Subject Device Model** **Terason 5V1A Transducer**	**Comparable Predicate Device** **Terason 4V2A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K150533	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Cephalic, and Cardiac	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Cephalic, and Cardiac	**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:	Phased Array	Phased Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 64 2.8 256 microns X 12mm 16.3mm	 64 2.8 256 microns X 12mm 16.3mm	**Same.** Identical pitch and center frequency. External components are used in the 5V1A to tune the transducer array.
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 (K150533).	**Same:** The 5V1A uses the 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 Valox	Silicone Valox	**Same**: Biocompatible.

Discussion:

The 5V1A uses the same acoustic array materials as the predicate (4V2A) 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 transducer has been added to the uSmart3200T Ultrasound system.

The 5V1A 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 15L4A

Key Features	**Subject Device Model** **Terason 15L4A Transducer**	**Comparable Predicate Device** **Terason 12L5A**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K150533	n/a
Indications for Use	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. Ophthalmic is the new IFU.	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. Ophthalmic included.	**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	Linear	Linear	**Same.**
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x elevation)…** **Elevation focus…**	 128 7.5 MHz 0.3mm X 4.25mm 16mm	 128 7.5 MHz 0.3mm X 4mm 13mm	**Different.** Different element size and elevation focus.
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) filings (K150533).	**Same.**
Patient Contact Material	RTV 630	Silicone	**Different.** The 15L4A and the predicate 12L5A transducers are both manufactured by Apex and consist of comparable patient contact materials.

Discussion:

The 15L4A transducer exhibits a wider frequency range than the predicate device used in this comparison. The transducer has been added to the uSmart3200T Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15L4A transducer is substantially equivalent to the predicate 12L5A transducer with respect to safety and effectiveness.

16L5 Transducer

Key Features	**Subject Device Model** **Terason uSmart3200T 16L5 Transducer**	**Comparable Predicate Device** **Terason 15L4 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K150533	n/a
Indications for Use	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.	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…**	 192 10 MHz 0.2mm X 3.5mm 16mm	 128 7.5 MHz 0.3mm X 4mm 16mm	**Different.** The new transducer has 64 more elements operating at a higher nominal center frequency.
Acoustic Array	The transducer performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filings (K150533).	**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	Silicone R1001	**Same.** The 16L5 transducer consists of a comparable patient contact material as the predicate device.

Discussion:

There 16L5 has more elements operating at a higher frequency than the predicate device used in this comparison. The transducer has been added to the uSmart3200T Ultrasound system.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 16L5 transducer is substantially equivalent to the predicate 15L4 transducer with respect to safety and effectiveness.

15WL4 Transducer

Key Features	**Subject Device Model** **Terason 15WL4 Transducer**	**Comparable Predicate Device** **Terason 15L4 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K150533	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) 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)…**	 192 9.0 MHz 0.3mm X 4mm	 128 7.5 MHz 0.3mm X 4mm	**Different.** Additional 64 elements operating at a higher frequency.

Elevation focus…	16mm	16mm	
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 (K150533).	**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 15WL4 has an additional 64 elements that operate at a higher frequency than the predicate device. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The 15WL4 transducer used with the uSmart3200T 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 15WL4 transducer meets safety and effectiveness guidelines.

XY-Biplane Transducer

Key Features	**Subject Device Model** **Terason Biplane Transducer**	**Comparable Predicate Device** **Terason 15L4 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K150533	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Cephalic, and Cardiac.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Abdominal, Pediatric, Musculo-skeletal, Peripheral Vascular.	**Different.** Different indications for use.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Different.** Different array types but same manufacturer (Vermon).
Acoustic Array Style:	Biplane Phased Array	Linear Array	
Acoustic Array Characteristics: **Element count…** **Center frequency…** **Element size (pitch x**	 128 (2 x 64 orthogonal) 2.8 MHz 0.28mm X 18mm	 128 7.5 MHz 0.3mm X 4mm	**Different.** Biplane operates at a lower frequency. Identical number of linear elements, however, in a different configuration.

elevation)… **Elevation focus…**	TBD	16mm	Significantly taller elements with comparable width.
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 (K150533).	**Same.** As the predicate device and therefore has identical 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 XY-Biplane transducer is a dual phased array made by the same manufacturer as the 15L4 transducer (Vermon). To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard. The Biplane transducer used with the uSmart3200T 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 Biplane transducer meets safety and effectiveness guidelines.

10EC4 Transducer

Key Features	**Subject Device Model** **Terason 10EC4 Transducer**	**Comparable Predicate Device** **Terason 8EC4A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K150533	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Trans-rectal, Trans-vaginal.	The 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:	Micro-convex	Micro-convex	
Manufacturer:	Vermon	Apex	**Different:** New manufacturer for EC transducer.
Acoustic Array Characteristics:			**Different.** The new 10EC4 provides

Element count… **Center frequency…** **Element size (pitch x elevation)…** **ROC** **Elevation focus…**	192 7.2 MHz 0.144mm X 6mm 8.8mm 35mm	128 6.5 MHz 0.205mm X 5mm 10mm 16mm	higher frequency response. 192 elements with finer pitch and larger elevation aperatures are used in the new transducer. The elevation focus is over 2:1.
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 (K150533).	**Same.** To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	SI 67	RTV 664	**Different.** Different Silicone material. The material has passed biocompatibility tests.

The 10EC4 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 10EC4 transducer used with the uSmart3200T 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 10EC4 transducer meets safety and effectiveness guidelines.

Previously filed transducers:

The following transducers are identical to those previously cleared under FDA 510(k) K150533, May 9, 2015 for the Terason uSmart3200T:

- 4V2
- 5C2A
- 8EC4A
- 12L5A
- 15L4
- 16HL7
- 8L2
- 8TE3
- 8V3A
- 9MC3
- PDOF.

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 and predicate device both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3200T 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 ultrasound system is substantially equivalent with regards to safety and effectiveness to the predicate device.

8. Summary of Bench Tests and Non-Clinical Tests

The Terason uSmart3200T 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

- 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 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 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.

9. Summary of Conclusions

The predicate system (uSmart3200T, K150533) and associated predicate transducers (Terason 4V2A, 12L5A, 15L4, 8EC4A) are legally marketed. The new system and associated transducers have the same intended use as the predicate system and devices. The Terason uSmart3200T and associated transducers represent a new implementation of familiar technology and therefore possess new technological characteristics that are validated in this filing.