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K140524
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510(k) Summary or Statement

Teratech Corporation

Terason uSmart3200T and BenQ UP200 Ultrasound System

1. **Sponsor:**

Teratech Corporation
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Burlington, MA 01803

Contact Person: Ben Chiampa
Director of Quality Assurance
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Date Prepared: February 18, 2014

2. **Device Name**

Proprietary Name: Terason uSmart3200 and BenQ UP200 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 (K131209)
Terason™ t3000 Ultrasound System (K112953)
Terason™ T3200 Ultrasound System (K110020)

4. **Intended Use**

The Teratech Corporation Terason™ uSmart3200T (also known as the BenQ UP200) 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: Fetal, Abdominal, Intra-Operative (abdominal, organs and vascular), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

5. **Device Description**

The Terason uSmart3200T ultrasound system is a portable tablet style full feature, general purpose, and 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 version of the uSmart3200T Ultrasound Systems. The modification includes the addition of 3 transducers (15L4, 16HL7, and 8EC4A) with the no change to tablet style computer form factor.

The Terason™ uSmart3200T ultrasound system was the previously cleared on the date of May 28, 2013 as described in the 510(k) submission (K131209). This system contains a proprietary ultrasound engine for controlling the acoustic output of the transducer and processing the return echoes in real time. This data are then transferred to the tablet computer over a FireWire (aka IEEE 1394) connection for further processing and generation and 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 same to the Terason uSmart3200T Ultrasound system which was cleared in May 2013. These systems utilize a portable computer running Windows to run the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. The engine is housed in a compartment that is attached to the bottom of the tablet computer.

The uSmart3200T system contains the same ultrasound engine as the predicate device Terason T3200 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 FireWire 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:

- Three transducers have been added to the system. The software has been modified to control these transducers and ensure compliance to the standards controlling acoustic and thermal power.
- Added support for 15L4, 16HL7 and 8EC4A transducers
  - Confirmed transducer id numbers and names
  - Confirmed transducer geometries and characteristic parameters
  - Confirmed 15L4 and 16HL7 acoustic tables and added 8EC4A acoustic tables
  - Added 15L4, 16HL7 and 8EC4A to the table of allowed transducers
  - Added imaging presets for 15L4, 16HL7 and 8EC4A with
    - Musculoskeletal selections same as offered on Terason t3200
    - 8EC4A gynecological and prostate exams
    - 15L4 same exam and preset selections as 12L5A
    - Vascular exams and presets for 15L4 and 16HL7

- Added the Vascular Application series with new exam license files
- Added exam license files for gynecological and prostate exam types
- Added the Enhanced Needle Visualization (ENV) feature as a licensed option, available only on the 15L4 transducer
- Added UI feature to optionally swap position of the Control Panel Area and the Thumbnail Area on the screen, left vs. right
- Removed TGC Display from the General tab of Setup
- Added System Backup and Restore, initiated from the General tab of Setup
- Added Gesture options to the General tab of Setup
  - Disable All Gestures
  - Enable Double Tap Gesture
- ECG options disable on General Tab of Setup
- Added measurement configurations for Spectral Doppler and M-mode.
- Added vessel name to the measurement configuration
- Added feature to modify user annotations
- In the Store/Acquire tab of Setup, added feature to enable retrospective acquisition of the live image stream
- Disabled selection of ECG related features on the Store/Acquire tab of Setup
- Added DICOM communication option and features, Storage and Modality Worklist
- Changed designation of Clinician to Operator on the Patient screen
- Added selection checkboxes to multiple selection list controls
- Added touch gestures for multiple selection in list controls
- Added touch gestures for freeze, play/pause, zoom and pan, depth, steering, split-screen, spectral Doppler scale and baseline, color Doppler scale, review navigation, full screen, text and body markers
- Added variable sector size and position for the 4V2A transducer
- Minor updates to soft key menus
- Modified 12L5A Musculoskeletal presets to be the same selections as offered on the Terason t3200
- Added Musculoskeletal, Breast, Thyroid and Vascular Access exam measurements and annotations, same as offered on Terason t3200.

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

Terason uSmart3200T System and Transducers Comparison and Discussion
(Transducers 8EC4A, 16HL7, and 15L4) and previously cleared 510(k) K131209 transducers (12L5A, 5C2A, and 4V2A)

Terason uSmart3200T Tablet Computer

	Subject Device Model **Terason uSmart3200T** **(This Submission)**	**Comparable Predicate Device** **Terason uSmart3200T** **K1301209**	**Comparable Predicate Devices** **Terason t3000** **K112953**

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	Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Peripheral vessel	Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Peripheral vessel	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, Peripheral vessel
Transducer Types	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear	Linear Array Curved Array Phased Array Endocavity – curved array	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Bi-plane –Linear/curved
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: TIC (15L4) TI Value: 5.8 (15L4) MI: 1.78 (8EC4A) $I_{PA.3}$@MI Max: 1029 W/cm^2 (15L4)	$I_{SPTA.3}$: 652.9 mW/cm^2 (4V2A) TI Type: TIB (4V2A) TI Value: 5.6 (4V2A) MI: 1.74 (4V2A) $I_{PA.3}$@MI Max: 350.3 W/cm^2 (4V2A)	$I_{SPTA.3}$: 678.1 mW/cm^2 (12HL7) TI Type: TIB (4V2A) TI Value: 5.6 (4V2A) MI: 1.5 (4V2A) $I_{PA.3}$@MI Max: 227.3 W/cm^2 (4V2A)
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	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	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 I

	Postprocessing	Postprocessing	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	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 – 10.0 MHz
#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 3.0 Worklist - Image Viewer
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	**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 Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**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 Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**Terason T3000:** Laptop Computer weighs: 8.0 pounds (3.6 kg), LED backlit display and keyboard, Laptop dimensions (H): 2.5", (W): 13.8", (D): 11.0" A Lithium-Polymer battery, (integrated into the Laptop) provides 2 hours of continuous ultrasound scanning. Uses a medical-grade power supply Data transferred to the laptop computer over a FireWire (aka IEEE 1394)

There are no hardware design changes to the system (ultrasound engine and tablet computer). The hardware design released at the time original submission (K131209) already had all the necessary functions and features to support the changes in software and the additional 3 transducers. The hardware revisions of the ultrasound engine and tablet computer remain unchanged.

8EC4A Transducer

Key Features	Subject Device Model Terason 8EC4A Transducer	Comparable Predicate Device Terason 8EC4A 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 uSmart3200T) to image trans-rectal and trans-vaginal.	The transducer is intended to be used with a conventional ultrasound system (Terason t3000) to image trans-rectal and trans-vaginal.	**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.** **Effectiveness**: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Endocavity Curved Array	Endocavity Curved Array	
Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	128 6.5 0.205mm X 5.0mm 30mm	128 6.5 0.205mm X 5.0mm 30mm	**Same:** element count. 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 8EC4A uses a same acoustic array 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	ABS Silicone 747	ABS Silicone 747	**Same**

Discussion:
The 8EC4A uses a same acoustic array 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.

The 8EC4A 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

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Transducer 16HL7

Key Features	**Subject Device Model** **Terason 16HL7 Transducer**	**Comparable Predicate Device** **Terason 16HL7 Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K110020	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image intra-operative, small parts, muskulo-skel and peripheral vascular regions.	The transducer is intended to be used with a conventional ultrasound system (Terason t3200) to image intra-operative, small parts, muskulo-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**
Transducer Style	Hockey-Stick Linear Array	Hockey-Stick Linear Array	**Same.**
Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	128 9.2 MHz 0.2mm X 3.5mm 12mm	128 9.2 MHz 0.2mm X 3.5mm 12mm	**Same.**
Acoustic Output and Device Settings	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K110020).	**Same.**

Patient Contact Material	Silicone PEI	Silicone PEI	**Same.**

Discussion:

There are no differences between this device and 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 16HL7 transducer is substantially equivalent to the Terason 16HL7 transducer (K110020) with respect to safety and effectiveness.

15L4 Transducer

Key Features	**Subject Device Model Terason 15L4 Transducer**	**Comparable Predicate Device Terason 15L4 Transducer**	**Same or Different**
510(k) Number	K140524	K110020	n/a
Classification	ITX	ITX	**Same**
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image abdomen, small parts, musculo-skel and peripheral vascular regions.	The transducer is intended to be used with a conventional ultrasound system (Terason T3200) to image abdomen, 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:** Safety requirements of IEC60601 are equally met. **Effectiveness:** 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 elements 7.5 MHz 0.3mm X 4.0mm 20mm	128 elements 7.5 MHz 0.3mm X 4.0mm 20mm	**Same:** element count. Acoustic characteristics have met safety guidelines of IEC60601-2-37.
Acoustic Output and Device Settings	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K110020).	**Same;** acoustic output safety guidelines. Safety is not compromised. Effectiveness equal.
Patient Contact Material	The transducer uses Silicone SIM R1001 as a contact material.	The transducer uses Silicone SIM R1001 as a contact material.	**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 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 identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15L4 transducer is substantially equivalent to the Terason 15L4 transducer (K110020) with respect to safety and effectiveness.

Transducers previously cleared in submission K131209

12L5A Transducer

Key Features	Subject Device Model **Terason 12L5A**	Comparable Predicate Device **Terason 12L5A**	Same or Different

	Transducer	Transducer	
Device Classification	ITX	ITX	**Same**
510(k) Number	KXXXXX	K131209	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, Musculo-skel, Cardiac and Peripheral vessel.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, Musculo-skel, Cardiac, and Peripheral vessel.	**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 7.5 0.3mm X 4.0mm 19mm	 128 7.5 0.3mm X 4.0mm 19mm	**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 (K131209).	**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.

5C2A Transducers

Key Features	**Subject Device Model** **Terason 5C2A Transducer**	**Comparable Predicate Device** **Terason 5C2A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K131209	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, Musculo-skel, Cardiac and Peripheral vessel.	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, Musculo-skel, Cardiac, and Peripheral vessel.	**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:	Curved Array	Curved Array	

Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	 128 3.5 0.5mm X 13.0mm 80mm	 128 3.5 0.5mm X 13.0mm 80mm	**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 (K131209).	**Same.** As the predicate device and therefore has different 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 5C2A transducer consists of same patient contact materials as the predicate device.

4V2A Transducer

Key Features	**Subject Device Model** **Terason 4V2A Transducer**	**Comparable Predicate Device** **Terason 4V2A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K131209	n/a
Indications for Use	The transducer is intended to be used with a conventional	The transducer is intended to be used with a conventional	**Same.** The proposed transducer and the predicate transducer

	ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, and Cardiac .	ultrasound system (Terason uSmart3200T) to image Fetal, Abdominal, Pediatric, Small Organ, Cephalic, and Cardiac.	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:	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 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 (K131209).	**Same.** As the predicate device and therefore has different 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.** The 4V2A transducer consists of same patient contact materials as the predicate device.

Accessories / Kits:

uSmart3200T Transducer	Accessory Description	Manufacturer / Part #	FDA 510k Clearance #
8EC4A	Biopsy Kit	Civco #610-605	K970514
8EC4A	Sterile Sheath	Civco # 610-001	K970513
16HL7	Sterile Sheath	Civco #610-797	K013721
15L4	Biopsy Kit	Civco #612-085	K882383/A
15L4	Sterile Sheath	Civco #610-002	K970513

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 predict devices both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3200T and predicate devices 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 devices as noted above.

8. Non Clinical Tests

The Terason uSmart3200T 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 Safety.
  - Intertek Test Record Number 100825075BOX-001.
- IEC 62366, Medical Devices: Application of usability engineering to medical devices.
  - Intertek Project: 100825075BOX-004A.
- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
  - Intertek Project: 100825075BOX-003A.
- 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
  - IEC60601-1-2 Test Record Number, 100933162BOX-017
  - Radiated Emissions CISPR11 Class B @10m Report Number 101224397BOX-001 on uSmart3200T 8EC4 and 16HL7
  - Radiated Emissions CISPR11 Class B @10m Report Number 101188849BOX-001a on uSmart3200T 15L4 Transducer

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
  - Transducer Model 15L4: Intertek Report #100404852BOX-002

  - Transducer Model 16HL7 Intertek Report #100404852BOX-004
  - Transducer Model 8EC4A Intertek Report #100404852BOX-003
- NEMA UD 3 Acoustic Output Display
  Terason uSmart3200T Ultrasound System User Guide (16-3301)
- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
  - Biocompatibility reports for the three new transducers included in this submission.
- AAMI TIR No. 12:210, Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers

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

March 21, 2014

TERATECH CORP.
% MARK JOB
RESPONSIBLE THIRD PARTY OFFICIAL
REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET NW
BUFFALO MN 55313

Re: K140524
Trade/Device Name: Terason uSmart3200T and BenQ UP200 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 20, 2014
Received: March 4, 2014

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.

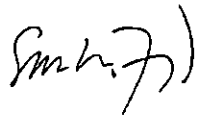
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for

Janine M. Morris
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 P R A Statement on last page.

510(k) Number *(if known)*
K140524

Device Name
Terason uSmart3200T and BenQ UP200 Ultrasound System

Indications for Use *(Describe)*
Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

The Teratech Corporation Terason™ uSmart3200T (also known as the BenQ UP200) 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: Fetal, Abdominal, Intra-Operative (abdominal, organs and vascular), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); 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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (C D R H) (*Signature*)

P S C Publishing Services (301) 443-6740 EF

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 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							
Fetal Imaging & Other	Fetal[h]	P'	P'	P'		P'	P'	P'
	Abdominal[d]:	P'	P'	P'		P'	P'	P'
	Intra-operative (Spec.)[d,e]	N	N	N		N	N	N
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P'	P'	P'		P'	P'	P'
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P'	P'	P'		P'	P'	P'
	Neonatal Cephalic[d]:	P'	P'	P'		P'	P'	P'
	Adult Cephalic[d]:	P'	P'	P'		P'	P'	P'
	Trans-rectal[i]:	N	N	N		N	N	N
	Trans-vaginal[g]:	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P'	P'	P'		P'	P'	P'
	Musculo-skel. (Superfic)[d]:	P'	P'	P'		P'	P'	P'
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P'	P'	P'		P'	P'	P'
	Cardiac Pediatric	P'	P'	P'		P'	P'	P'
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[f]:	P'	P'	P'		P'	P'	P'
	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.

[i] 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': uses previously cleared under K131209.

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

Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 – 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							
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 K110020

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 – 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

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 – 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

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 – 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[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Abdominal[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	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[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Musculo-skel. (Superfic)[d]:	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Cardiac Pediatric	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	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

P[2]: uses previously cleared under K131209

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 - 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							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Neonatal Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Adult Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Musculo-skel. (Superfic)[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	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

P[2]: uses previously cleared under K131209

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

Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3200T and BenQ UP200 - 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[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Abdominal[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Adult Cephalic[d]:	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	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[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Cardiac Pediatric	P[1,2]	P[1,2]	P[1,2]		P[1,2]	P[1,2]	P[1,2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[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

P[2]: uses previously cleared under K131209

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

Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)