K110482

510(k) Summary

Teratech Corporation

ProSound™ C3 Ultrasound System

MAR 18 2011

1. **Sponsor:**

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

Contact Person: Charles F. Hottinger, Ph.D, RAC,
Regulatory Affairs Consultant
Telephone: 206-780-7945

Date Prepared: October 9, 2010

2. **Device Name**

Proprietary Name: Aloka ProSound C3 Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

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

3. **Predicate Device**

Terason™ Echo/t3000 Ultrasound System (K080234)

4. **Intended Use**

The Aloka ProSound C3 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, thoracic and PV); Pediatrics, Small Organ (Breast, testes, thyroid); Neonatal and Adult Cephalic;

Trans-rectal and Trans-vaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

5. Device Description

The ProSound C3 is a modified version of the Echo/t3000 Ultrasound System. The modifications include a change in the Product Label (of both the systems and the transducers), addition of Foreign language support (French, German, Italian, and Spanish), a slight modification of Transmit circuitry, providing a slightly different acoustic profile and the introduction of a spatial compounding feature called OMNIBeam .

6. Technology Characteristics

The design and construction of the ProSound C3 is similar to the Terason™ Echo/t3000 Ultrasound system. These systems utilize a laptop 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 laptop.

The differences between the ProSound C3 and the Terason Echo/t3000 Ultrasound System (the predicate device) include the following:

- The engine has a slight modification to the Transmit Chip, providing different acoustic prodiles. This has been optimized for the ProSound C3 and tested and verified according to the IEC 60601.2.37 standards.
- The ultrasound application software has been modified to support foreign languages (French, German, Italian and Spanish). Translations were made for buttons, pulldown menus, text messages, etc. and integrated and tested with the application software.
- A new feature, equivalent to spatial compounding, was added to the application software (since the last 510k submission on the predicate device). This feature, called OMNIBeam in the ProSound C3 is used for better resolution by shooting multiple frames at different angles and combining the image into one. This is offered on only the Linear and Curved transducers.
- The System has a different label (Aloka ProSound C3 label) and the transducers have different names and labels than the predicate device. Other than the labels, the transducers are exactly the same as those used on the Terason Predicate Device.

B1. Non Clinical Tests

The ProSound C3 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 3157931BOX-001B

- IEC 60601-1-1, Medical Electrical Equipment Part 1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems.
    - Intertek Project: 9157933BOX-002A

- IEC60601-1-4 (2000), Collateral Standard: Safety Requirements for Medical Electrical Systems
    - Intertek Project: 9157933BOX-003A

- 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 UST-TL01: Intertek Report Number 9157931BOX-001M
    - Transducer Model UST-TL02: Intertek Report Number 9157931BOX-001N
    - Transducer Model UST-TC04: Intertek Report Number 9157931BOX-001Q
    - Transducer Model UST-TC05: Intertek Report Number 9157931BOX-001P
    - Transducer Model UST-TC06: Intertek Report Number 9157931BOX-001J
    - Transducer Model UST-TL07: Intertek Report Number 9157931BOX-001O

- NEMA UD 3 Acoustic Output Display
  ProSound C3/C3cv Ultrasound System User Guide (16-5001)

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
    - Biocompatibility reports for all transducers included in this submission.

510(k) Summary

Teratech Corporation

ProSound™ C3cv Ultrasound System

1. **Sponsor:**

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

Contact Person: Charles F. Hottinger, Ph.D, RAC,
Regulatory Affairs Consultant
Telephone: 206-780-7945

Date Prepared: October 9, 2010

2. **Device Name**

Proprietary Name: Aloka ProSound C3cv Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

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

3. **Predicate Device**

Terason™ Echo/t3000 Ultrasound System (K080234)

4. **Intended Use**

The Aloka ProSound C3cv 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, thoracic and PV); Pediatrics, Small Organ (Breast, testes, thyroid); Neonatal and Adult Cephalic;

Trans-rectal and Trans-vaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

5. Device Description

The ProSound C3cv is a modified version of the Echo/t3000 Ultrasound System. The modifications include a change in the Product Label (of both the systems and the transducers), addition of Foreign language support (French, German, Italian, and Spanish) and the introduction of a spatial compounding feature called OmniBeam .

6. Technology Characteristics

The design and construction of the ProSound C3cv is similar to the Terason™ Echo/t3000 Ultrasound system. These systems utilize a laptop 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 laptop.

The differences between the ProSound C3cv and the Terason Echo/t3000 Ultrasound System (the predicate device) include the following:

- The ultrasound application software has been modified to support foreign languages (French, German, Italian and Spanish). Translations were made for buttons, pulldown menus, text messages, etc. and integrated and tested with the application software.
- A new feature, equivalent to spatial compounding, was added to the application software (since the last 510k submission on the predicate device). This feature, called OMNIBeam in the ProSound C3cv is used for better resolution by shooting multiple frames at different angles and combining the image into one. This is offered on only the Linear and Curved transducers.
- The System has a different label (Aloka ProSound C3cv label) and the transducers have different names and labels than the predicate device. Other than the labels, the transducers are exactly the same as those used on the Terason Predicate Device (Terason Echo/t3000).

B1. Non Clinical Tests

The ProSound C3cv 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 3157931BOX-005A

- IEC 60601-1-1, Medical Electrical Equipment Part 1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems.
    - Intertek Project: 9157933BOX-002B

- IEC60601-1-4 (2000), Collateral Standard: Safety Requirements for Medical Electrical Systems
    - Intertek Project: 9157933BOX-003B

- 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 UST-TL01: Intertek Report Number 9157931BOX-005G
    - Transducer Model UST-TL02: Intertek Report Number 9157931BOX-005B
    - Transducer Model UST-TS03: Intertek Report Number 9157931BOX-005C
    - Transducer Model UST-TC04: Intertek Report Number 9157931BOX-005D
    - Transducer Model UST-TC06: Intertek Report Number 9157931BOX-005E
    - Transducer Model UST-TI09: Intertek Report Number 9157931BOX-005F

- NEMA UD 3 Acoustic Output Display
  ProSound C3/C3cv Ultrasound System User Guide (16-5001)

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
    - Biocompatibility reports for all transducers included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Teratech Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street NW
BUFFALO MN 55313

MAR 18 2011

Re: K110482
Trade/Device Name: Aloka Prosound C3 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: March 7, 2011
Received: March 8, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka Prosound C3 Ultrasound System, as described in your premarket notification:

Transducer Model Number

UST-TL01	UST-TC05
UST-TL02	UST-TC06
UST-TS03	UST-TL07
UST-TC04	UST-TI09

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Aloka ProSound C3 Ultrasound System

Indications for Use:

The subject-modified device 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/OB; Abdominal (GYN & Urology); Intra-operative (abdominal, thoracic and PV); Laparoscopic; Pediatric; Small Organ (breast, testes, thyroid), Neonatal and Adult Cephalic; Transrectal and Transvaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (adult & pediatric); Peripheral Vascular.

Prescription Use: X AND/OR Over-the-Counter Use:_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K110482

Indications for Use Form

510(k) Number (if known): _____

Device Name: Aloka ProSound C3cv Ultrasound System

Indications for Use:

The subject-modified device 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/OB; Abdominal (GYN & Urology); Intra-operative (abdominal, thoracic and PV); Laparoscopic; Pediatric; Small Organ (breast, testes, thyroid), Neonatal and Adult Cephalic; Transrectal and Transvaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (adult & pediatric); Peripheral Vascular.

Prescription Use: X AND/OR Over-the-Counter Use:_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K110482

System: ProSound C3/C3cv Ultrasound Systems
Transducer: (see comments)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Abdominal[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Intra-operative (Spec.)[d,e]	P[4,8]	P[4,8]	P[4,8]		P[4,8]	P[4,8]	P[4,8]
	Intra-operative (Neuro)	P[5]	P[5]	P[5]		P[5]	P[5]	P[5]
	Laparoscopic	P[6]	P[6]	P[6]		P[6]	P[6]	P[6]
	Pediatric[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Neonatal Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Adult Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Trans-rectal[f]:	P[2-4]	P[3-4]	P[3-4]		P[3-4]	P[3-4]	P[3-4]
	Trans-vaginal[g]:	P[2-4]	P[3-4]	P[3-4]		P[3-4]	P[3-4]	P[3-4]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Musculo-skel. (Superfic)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1,8]	P[2,8]	P[2,8]	P[7,8]	P[2,8]	P[2,8]	P[2,8]
	Cardiac Pediatric	P[1,8]	P[2,8]	P[2,8]	P[7,8]	P[2,8]	P[2,8]	P[2,8]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234); E= added under Appendix E
[a] Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).
[b] B+M; B+PWD; B+CD; B+DPD; B+PD
[c] Harmonic Imaging (HI)
[d] Incl. ultrasound guidance for placement of needles, catheters
[e] Abdominal organs and peripheral vessel.
[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.
[i] Incl. stress echo.
[1] System uses previously cleared under K992505 with 3MHz Model L3 (Linear)
[2] System uses previously cleared under K012191
[3] System uses previously cleared under K010883
[4] System uses previously cleared under K030191
[5] System uses previously cleared under K040840
[6] System uses previously cleared under K043278
[7] System uses previously cleared under K051334
[8] System uses previously cleared under K080234

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K110482

System: ____ProSound C3/C3cv Ultrasound System____

Transducer: UST-TL01

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[d]:	E	E	E		E	E	E
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	E	E	E		E	E	E
	Neonatal Cephalic[d]:	E	E	E		E	E	E
	Adult Cephalic[d]:	E	E	E		E	E	E
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	E	E	E		E	E	E
	Musculo-skel. (Superfic)[d]:	E	E	E		E	E	E
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:	E	E	E		E	E	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K110482

System: ____ProSound C3/C3cv Ultrasound System____

Transducer: UST-TL02

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[e]:	E	E	E		E	E	E
	Intra-operative (Spec.)[a,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[e]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast, Testes, etc.)[e]:	E	E	E		E	E	E
	Neonatal Cephalic[e]:	E	E	E		E	E	E
	Adult Cephalic[e]:	E	E	E		E	E	E
	Trans-rectal[i]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[e]:	E	E	E		E	E	E
	Musculo-skel. (Superfic)[e]:	E	E	E		E	E	E
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:	E	E	E		E	E	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110482

System: ___**ProSound C3cv Ultrasound System**___

Transducer: UST-TS03

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	E	E	E		E	E	E
	Abdominal[o]:	E	E	E		E	E	E
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	E	E	E		E	E	E
	Adult Cephalic[d]:	E	E	E		E	E	E
	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	E	E	E	E	E	E	E
	Cardiac Pediatric	E	E	E		E	E	E
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110482

System: ___ProSound C3/C3cv Ultrasound System____

Transducer: UST-TC04

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	E	E	E		E	E	E
	Abdominal[d]:	E	E	E		E	E	E
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	E	E	E		E	E	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K110482

System: ____ProSound C3 Ultrasound System____

Transducer: UST-TC05

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	E	E	E		E	E	E
	Abdominal[o]:							
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	E	E	E		E	E	E
	Neonatal Cephalic[d]:	E	E	E		E	E	E
	Adult Cephalic[d]:	E	E	E		E	E	E
	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	E	E	E		E	E	E
	Cardiac Pediatric	E	E	E		E	E	E
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	E	E	E		E	E	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K110482

System: ____ProSound C3/C3cv Ultrasound System____

Transducer: UST-TC06

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	E	E	E		E	E	E
	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]:	E	E	E		E	E	E
	Trans-vaginal[g]:	E	E	E		E	E	E
	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[c]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[n] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K110482

System: ____ProSound C3 Ultrasound System____

Transducer: UST-TL07

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[q]:							
	Intra-operative (Spec.)[d,e]	E	E	E		E	E	E
	Intra-operative (Neuro)	E	E	E		E	E	E
	Laparoscopic	E	E	E		E	E	E
	Pediatric[q]:	E	E	E		E	E	E
	Small Organ (Thyroid, Breast. Testes, etc.)[q]:	E	E	E		E	E	E
	Neonatal Cephalic[q]:							
	Adult Cephalic[q]:							
	Trans-rectal[l]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[q]:	E	E	E		E	E	E
	Musculo-skel. (Superfic)[q]:	E	E	E		E	E	E
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	E	E	E		E	E	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[l] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(k) K110482

System: ____ProSound C3cv Ultrasound System____

Transducer: UST-TI09

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[e]:							
	Intra-operative (Spec.)[d,e,j]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[e]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[e]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[e]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult				E			
	Cardiac Pediatric				E			
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA (incl. K080234; E= added under Appendix E

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

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

[1] System uses previously cleared under K992505 with 3MHz. Model L3 (Linear)

[2] System uses previously cleared under K012191

[3] System uses previously cleared under K010883

[4] System uses previously cleared under K030191

[5] System uses previously cleared under K040840

[6] System uses previously cleared under K043278

[7] System uses previously cleared under K051334

[8] System uses previously cleared under K080234

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K110482