AUG 2 2012

PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. **Company Name:**

Submitter: Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact: Ms. Ruoli Mo
Tel: +86-510-85311707, 85310593 Fax: +86-510-85310726

Date Prepared: May 22,2012

2. **Device Name:** SonoTouch Series Diagnostic Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. **Marketed Device:**
K102256,GE LOGIQ e Ultrasound System

3. **Device Description:**
The SonoTouch Series device is a compact and extremely portable ultrasound system consisting of a hand-carried console with the ability to dock it with a Docking station or mobile Docking cart.The primary means of control is graphical user interface implemented by a touch sensitive screen over the color LED display providing additional command input and keyboard entry. It utilizes interchangeable electronic-array transducers operating B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, or a combination of these modes. with digital acquisition, processing and display capability operating under a Linux OS. Powered by an integrated battery or from a separate power supply in the docking station or docking cart, the SonoTouch Series is used primarily where portability, size and convenience are

essential.

The SonoTouch Series Models, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Comparison to Predicate Device:

The SonoTouch Series Models is of comparable type and substantially equivalent to the GE LOGIQ i, LOGIQ e,Vivid e Diagnostic Ultrasound(K102256) . All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

5. Conclusion:

The SonoTouch Series Models is substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 2 2012

CHISON Medical Imaging Co., Ltd.
% Mr. Michael S. Ogunleye
Third Party Program Manager/Lead Medical Auditor
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K121867
Trade/Device Name: SonoTouch Series Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 25, 2012
Received: July 25, 2012

Dear Mr. Ogunleye:

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 SonoTouch Series Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

C3, Convex Array
MC3, Micro-convex Array
V6, Micro-convex Array
L7M, Linear Array
L7S, Linear Array
R7, Linear Array
L7L, Linear Array
P3, Phased Array
MC5V, Convex Array
MC6, Convex Array

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 Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

for

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use

1.3 Indications for Use

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

(Division Sign-Off)
Division of Radiological Devices
DIVD
510k K121857

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications For Use

System: SonoTouch Series Diagnostic Ultrasound Systems

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1
	Cardiac Pediatric	N	N	N	N	N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Comments:

Small Organ: Thyroid, testes and breast

Additional Comments:

Prescription Use √ AND/OR Over-The-Counter Use ___

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Radiological Devices

OIVD

510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: C3, Convex Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Comments:

Small Organ: Thyroid, testes and breast

Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: MC3, Micro-convex Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast

Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: V6, Micro-convex Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510k Section 1.3 K121867 Indications For Use

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: L7M, Linear Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: L7S, Linear Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k K121807 OIVD

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: R7, Linear Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: L7L, Linear Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k K121887

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: P3, Phased Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1
	Cardiac Pediatric	N	N	N	N	N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD

510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: MC5V, Convex Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510k K121867

System: SonoTouch Series Diagnostic Ultrasound Systems
Transducer: MC6, Convex Array

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Comments:
Small Organ: Thyroid, testes and breast
Additional Comments:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices

510k K121867