



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Beijing East Whale Imaging Technology Co., Ltd.
% Ms. June Li
RA Manager
B2-2 New City Industrial Park,
No.9 KeChuang 2nd St.
YiZhuang, Beijing 100023
CHINA

April 7, 2016

Re: K160343
Trade/Device Name: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound
Diagnostic Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 3, 2016
Received: February 8, 2016

Dear Ms. Li:

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 Industry and Consumer Education 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” (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a slight shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160343

Device Name
SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner

Indications for Use (Describe)

The Portable Ultrasound Diagnostic Scanner is intended for use by, or under the direction of, a qualified physician for ultrasound imaging and analysis in Abdomen; Small Parts; Obstetrics; Gynecology; Cardiology; Peripheral Vessels; Urology; Pediatrics; Neonate; Trans-cranial; Musculoskeletal; Fetal; Intra-operative; Transvaginal.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Indications for Use Form

System: LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 1P4V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic								
Fetal	N	N	N	N	N	N	Note 1	Notes 2,3
Abdominal	N	N	N	N	N	N	Note 1	Notes 2,3
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
Small Organ (specify)								
Neonatal Cephalic								
Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)								
Intravascular								
Other (Ob/GYN)	N	N	N	N	N	N	Note 1	Notes 2,3
Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3
Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
Intravascular(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3
Trans-esoph.(Cardiac)								
Intra-cardiac								
Other (specify)								
Peripheral vessel								
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Color Doppler/PWD;
B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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Office of *In Vitro* Diagnostic and Radiological Health

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Diagnostic Ultrasound Indications for Use Form

System: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 2P4V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic								
Fetal	N	N	N		N	N	Note 1	Notes 2,3
Abdominal	N	N	N		N	N	Note 1	Notes 2,3
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric	N	N	N		N	N	Note 1	Notes 2,3
Small Organ (specify)								
Neonatal Cephalic								
Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)								
Intravascular								
Other (Ob/GYN)	N	N	N	N	N	N	Note 1	Notes 2,3
Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3
Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
Intravascular(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3
Trans-esoph.(Cardiac)								
Intra-cardiac								
Other (specify)								
Peripheral vessel								
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

System: OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 3P8V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	N	N	N	N	N	N	Note 1	Notes 2,3
Fetal	N	N	N	N	N	N	Note 1	Notes 2,3
Abdominal	N	N	N	N	N	N	Note 1	Notes 2,3
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
Small Organ (specify)	N	N	N	N	N	N	Note 1	Notes 2,3,4
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)	N	N	N	N	N	N	Note 1	Notes 2,3
Musculo-skeletal (Superficial)	N	N	N	N	N	N	Note 1	Notes 2,3
Intravascular	N	N	N	N	N	N	Note 1	Notes 2,3
Other (Ob/GYN)								
Cardiac Adult								
Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
Intravascular(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3
Trans-esoph.(Cardiac)								
Intra-cardiac	N	N	N	N	N	N	Note 1	Notes 2,3
Other (specify)								
Peripheral vessel	N	N	N	N	N	N	Note 1	Notes 2,3
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

System: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 2C5V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic								
Fetal	N	N	N		N	N	Note 1	Notes 2
Abdominal	N	N	N		N	N	Note 1	Notes 2
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric	N	N	N		N	N	Note 1	Notes 2
Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral	N	N	N		N	N	Note 1	Notes 2
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
Intravascular	N	N	N		N	N	Note 1	Notes 2
Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2
Cardiac Adult								
Cardiac Pediatric	N	N	N		N	N	Note 1	Notes 2
Intravascular(Cardiac)								
Trans-esoph.(Cardiac)								
Intra-cardiac								
Other (specify)								
Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

System: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 4EC9V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic								
Fetal	N	N	N	N	N	N	Note 1	Notes 2,3
Abdominal	N	N	N		N	N	Note 1	Notes 2
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric								
Small Organ (specify)								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	Note 1	Notes 2
Trans-vaginal	N	N	N		N	N	Note 1	Notes 2
Trans-urethral	N	N	N		N	N	Note 1	Notes 2
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)								
Musculo-skeletal (Superficial)								
Intravascular								
Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2
Cardiac Adult								
Cardiac Pediatric								
Intravascular(Cardiac)								
Trans-esoph.(Cardiac)								
Intra-cardiac								
Other (specify)								
Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

System: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound Diagnostic Scanner with 12L5V probe

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

Clinical Application Anatomy/Region of Interest	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	N	N	N		N	N	Note 1	Notes 2
Fetal								
Abdominal	N	N	N		N	N	Note 1	Notes 2
Intra-operative Specify								
Intra-operative Neuro								
Laparoscopic								
Pediatric	N	N	N	N	N	N	Note 1	Notes 1
Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card)								
Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
Intravascular								
Other (Ob/GYN)								
Cardiac Adult								
Cardiac Pediatric								
Intravascular(Cardiac)								
Trans-esoph.(Cardiac)								
Intra-cardiac								
Other (specify)								
Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: Small Organ: breast, thyroid, testes

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510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

Apr 6th 2016

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Beijing East Whale Imaging Technology Co., Ltd.

Address: B2-2 New City Industrial Park, No.9 KeChuang 2nd St.,
YiZhuang, 100023, Beijing, China.

Contact Name: June Li

Telephone No.: + 86 (10) 67892355- 8968

Fax No.: + 86 (10) 67082218

Email Address: jqli@whaleimaging.com

3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Common Name: Portable Ultrasound Diagnostic Scanner

Model: P5/ P7/ P9

Trade Name: SIGMA P5/ OMEGA P7/ LAMBDA P9 Portable Ultrasound
Diagnostic Scanner

Classification Name: Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System

Diagnostic Ultrasound Transducer

Classification Regulation: 892.1550/ 892.1560/ 892.1560

Product code: IYN/ IYO/ ITX

Classification Panel: Radiology

Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

510(k) Number	K102388
Applicant	GE Healthcare [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC]
Device Name	Vivid i and Vivid q Diagnostic Ultrasound System

5. Description of the Device [21 CFR 807.92(a)(4)]

The Portable Ultrasound Diagnostic Scanner comprises of a console, a cart, an AC adaptor, and several transducers and printers. The console is a portable ultrasound diagnostic device with an integrated keyboard and LCD display. It is capable of digital acquisition, processing and display. The mobile cart with multiple socket-outlet and extension transducer connector improves the mobility by having all accessories on it.

6. Intended Use [21 CFR 807.92(a)(5)]

The Portable Ultrasound Diagnostic Scanner is intended for use by, or under the direction of, a qualified physician for ultrasound imaging and analysis in Abdomen; Small Parts; Obstetrics; Gynecology; Cardiology; Peripheral Vessels; Urology; Pediatrics; Neonate; Trans-cranial; Musculoskeletal; Fetal; Intra-operative; Transvaginal.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The Portable Ultrasound Diagnostic Scanner employs the same fundamental technological characteristics as its predicate devices.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Results of performance and compliance testing conducted on Portable Ultrasound Diagnostic Scanner, indicates conformance to all applicable standards recognized by FDA for this device.

Based on non-clinical test results, Portable Ultrasound Diagnostic Scanner is substantially equivalent to predicate devices in safety and effectiveness.

Non-clinical testing:

The proposed device has been tested to compliance to the following safety and performance standards:

AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012

IEC 60601-1-2: 2007

IEC 60601-2-37: 2007

NEMA UD 2: 2004

ISO 10993-5:2009

ISO 10993-10:2010

Comparison with Predicated Device:

The proposed device is substantially equivalent in safety and effectiveness to the proposed device:

Items	Proposed Device	Predicate Device	Remark
Intended Use	The Portable Ultrasound Diagnostic Scanner is intended for use by, or under the direction of, a qualified physician for ultrasound imaging and analysis in Abdomen;	the Vivid ilq ultrasound systems are intended for use by, or under the direction of, a qualified physician for ultrasound imaging and analysis in Abdominal/GYN; Urology;	Note 1

	Small Parts; Obstetrics; Gynecology; Cardiology; Peripheral Vessels; Urology; Pediatrics; Neonate; Trans-cranial; Musculoskeletal; Fetal; Intra-operative; Transvaginal.	Fetal/OB3; Small Organ (breast, testes, thyroid); Pediatric; Neonatal & Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculo-skeletal (conventional & superficial); Transesophageal; Intraoperative (abdominal, thoracic and PV); Transvaginal and Transrectal, Intra-cardiac and intra-luminal applications.	
Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Same
Product Code	IYN/ IYO/ ITX	IYN/ IYO/ ITX	Same
Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	Same
Panel	Radiology	Radiology	Same
Class	II	II	Same
Probe Type	1P4V, Phrased Array	3Sc-RS , Phased Array	Same
	2P4V, Phrased Array	3S-RS , Phased Array	
	3P8V, Phrased Array	7S-RS, Phased Array	
	2C5V, Convex Array	3C-RS, Convex Array	
	12L5V, Linear Array	8L-RS, Linear Array	
	4EC9V, Intracavitary Convex Array, 4-9MHz	e8C-RS, Intracavitary Convex Array, 4.0 - 11.0 MHz	

Acoustic Track	TRACK 3	TRACK 3	Same
Imaging mode	2D(B) mode, M-Mode, AMM-Mode, Color Doppler, Power Doppler (Angio), Tissue Velocity Imaging (TVI) mode, PW mode, CW mode, Tissue-Doppler imaging (TVD) mode, TDI, and some application functions	2D (B) Mode, Color Doppler, Power Doppler (Angio), M-Mode, Color M-Mode, PW and CW Doppler spectra, Tissue-Doppler imaging (TDI) and LVO Contrast option applications	Same
Power Supply	Voltage: 110-240 VAC	Voltage: 110-240 VAC	Same
	Frequency: 50/60 Hz	Frequency: 50/60 Hz	
Acoustic Output	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max	Track 3: MI,TIS,TIC,TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max	Same
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Performance	IEC 60601-2-37 NEMA UD 2: 2004	IEC 60601-2-37 NEMA UD 2: 2004	Same
Biocompatibility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	Same
Level of Concern Of Software	Moderate level of concern system	Moderate level of concern system	Same
Design	Console+Cart+Probe+ECG+ Printer DICOM	Console+Cart+Probe+ECG+ Printer DICOM	Same

Note 1: Intended use of proposed device is similar with predicate device. Applications of the predicate device cover all the applications of proposed device, and thus the difference will not affect safety and efficiency of device.

The proposed device has similar intended use, similar product design, similar performance effectiveness, and performance safety as the predicate device.

The differences between the proposed device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the proposed device.

And no new risk is raised regarding to effectiveness and safety.

The proposed device is substantial with the predicated device.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we concludes that Portable Ultrasound Diagnostic Scanner is substantially equivalent to predicate devices with regard to safety and effectiveness.