K128611

510(k) Summary

DEC 2 1 2012

In accordance with 21CFR807.92, the following summary of information is provided;

Date	Nov 13th 2012
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848
Primary Contact Person	Donghwan Kim QARA Manager Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848 Phone: +82 70 7465 2068 Fax: +82 2 851 5590 Email: donghwan.kim@alpinion.com
Secondary Contact Person	Yuchi Chu Address: Suite 229, 10604 NE 38th Place, Kirkland, WA 98033, United States Phone: 425 949 4907 Fax: 425 949 4908 Email: ychu@alpinionus.com
Device Trade Name:	E-CUBE 7
Common/Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Names	System, Imaging, Pulsed Doppler Ultrasonic
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX
Predicate Device(s)	K120060 E-CUBE 9 Diagnostic Ultrasound System
Device Description:	E-CUBE 7 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5" wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.
Indications For Use:	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult & pediatric); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE 7 employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

E-CUBE 7 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 7 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 7:

- Medical Device Risk Management
- Requirements Reviews
- Design Reviews
- Component Verification
- Integration Review (System Verification)
- Performance Testing (System Verification)
- Safety Testing (Compliance Test)
- Design Validation

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 7, did not require clinical studies to support substantial equivalence.

Conclusion: Alpinion Medical Systems Co., Ltd. considers E-CUBE 7 to be as safe, as effective. Performance, technology and software are substantially equivalent to the predicate device.

- The discussion about the technological and software differences between E-CUBE 7 and the predicate device: Some image parameters are added for operational convenience which means these parameters do not affect to the measurement accuracy. So there is no significant difference in essential performance, safety and effectiveness with the predicate device and the image parameter functions do not change the intended use.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Mr. Donghwan Kim
QARA Manger
Alpinion Medical Systems, Co., Ltd
1, 6 and 7FL, Verti Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu
Seoul, 152-848
REPUBLIC OF KOREA

Re: K123611
Trade/Device Name: E-Cube 7
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 21, 1012
Received: November 21, 2012

Dear Mr. Kim:

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.

This determination of substantial equivalence applies to the E-Cube 7 and the following transducers intended for use with the E-Cube 7 Ultrasonic pulsed Doppler Imaging System, as described in your premarket notification:

Transducer Model Number		
C1-6	E3-10	L3-12H
L3-12	VC1-6	SP3-8
SP1-5	L3-8	
EN3-10	SC1-6	

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 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.

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,

Janine M. Morris -S

Janine M. Morris
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):

Device Name: E-CUBE 7

Indications for Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult&pediatric); Peripheral Vascular (PV); and Urology (including prostate).

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Janine M. Morris -S
2012.12.21 11:07:34 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 Ultrasound System

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	N
Abdominal	P	P	P		P	P	P	P	N
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	N
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	P	P		P	P	N	P	
Trans-vaginal	P	P	P		P	P	N	P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	P	P	P		P	P	P	P	
Musculo-skeletal (***Superficial***)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult	P	P	P		P	P	P	P	
Cardiac Pediatric	N	N	N		N	N	N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)	P	P	P		P	P	P	P	N

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with C1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with L3-12 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	P	P	P		P	P	P	P	
Musculo-skeletal (*Superficial*)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with SP1-5 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult	P	P	P		P	P	P	P	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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510(k) k123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with EN3-10 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	P	P		P	P	N	P	
Trans-vaginal	P	P	P		P	P	N	P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	N	P	

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with E3-10 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	P	P		P	P		P	
Trans-vaginal	P	P	P		P	P		P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P		P	

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with VC1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	P
Abdominal	P	P	P		P	P	P	P	P
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	P
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	N

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with L3-8 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	N	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	N	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	P	P	P		P	P	N	P	
Musculo-skeletal (*Superficial*)	P	P	P		P	P	N	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	N	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with SC1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with L3-12H Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	N	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	N	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	P	P	P		P	P	N	P	
Musculo-skeletal (*Superficial*)	P	P	P		P	P	N	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	N	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611

Diagnostic Ultrasound Indications for Use

E-CUBE 7 with SP3-8 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric	P	P	P		P	P	P	P	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2012.12.21 11:27:39 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123611