DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 22, 2016

ALPINION MEDICAL SYSTEMS Co., Ltd.
% Mr. Donghwan Kim
Quality Management Representative (QMR)
1FL and 6FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu
Seoul 08393
REPUBLIC OF KOREA

Re: K161439
Trade/Device Name: E-CUBE 11
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 19, 2016
Received: August 22, 2016

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of September 21, 2016.

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161439

Device Name
E-CUBE 11

Indications for Use *(Describe)*

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); Adult Cephalic; Trans-rectal (TR); Trans-vaginal (TV); Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Cardiac Adult; Cardiac Pediatric; Peripheral Vascular (PV); and Urology (including prostate).

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

E-CUBE 11 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	N	N	N		N	N	N	N	N
Abdominal	N	N	N		N	N	N	N	N
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	N
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic	N	N	N		N	N	N	N	
Trans-rectal	N	N	N		N	N	N	N	N
Trans-vaginal	N	N	N		N	N	N	N	N
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	N	N	N		N	N	N	N	
Musculo-skeletal (***Superficial***)	N	N	N		N	N	N	N	
Intravascular									
Other (Specify)									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric	N	N	N	N	N	N	N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)	N	N	N		N	N	N	N	N

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

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with SC1-4HS 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									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with SC1-6H 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***)	N	N	N		N	N	N	N	
Musculo-skeletal (***Superficial***)	N	N	N		N	N	N	N	
Intravascular									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with SC1-4H 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									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 L3-12H^{WD} with 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)	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									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K132687; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 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									
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									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 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	N	N	N		N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult	P	P	P	P	P	P	P	P	
Cardiac Pediatric	N	N	N	N	N	N	N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K132687; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with MP3-8 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	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic	N	N	N		N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric	N	N	N	N	N	N	N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)									

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

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with SVC1-6H 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									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	N

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with EV3-10H 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	N	N	N		N	N	N	N	
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	P	
Trans-vaginal	P	P	P		P	P	P	P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with EC3-10H 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	N	N	N		N	N	N	N	
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	P	
Trans-vaginal	P	P	P		P	P	P	P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with VE3-10H 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	N	N	N		N	N	N	N	N
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	P	P
Trans-vaginal	P	P	P		P	P	P	P	P
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	P

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with CW2.0 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									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult				P					
Cardiac Pediatric				P					
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 11 with CW5.0 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									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Other (Specify)									
Cardiac Adult				P					
Cardiac Pediatric				P					
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K150773; E = added under appendix

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

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

Prescription User (Per 21 CFR 801.109)

510(k) Summary

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

Date	May 17th, 2016
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1FL and 6FL, Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, 08393, Republic of Korea
Primary Contact Person	Donghwan Kim Quality Management Representative(QMR) Address: 1FL and 6FL, Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, 08393, Republic of Korea Phone: +82 70 7465 2068 Fax: +82 2 6220 2162 Email: qa_ra@alpinion.com
Secondary Contact Person	JULIAN LEE Address: 21312 30th Dr SE Ste 100 Bothell, WA 98021, United States Phone: 425 949 1059 Fax: 425 949 4910 Email: julian.lee@alpinionusa.com
Device Trade Name:	E-CUBE 11
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
Primary Predicate Device	K150773 E-CUBE 15 Diagnostic Ultrasound System
Predicate Device	K153424 E-CUBE i7 Diagnostic Ultrasound System K132687 E-CUBE 7 Diagnostic Ultrasound System
Device Description:	E-CUBE 11 product is an ultrasound imaging system for medical diagnosis. This innovative system platform provides optimal patient diagnosis workflow with the wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

1. Signal Mode:
2D(B) mode, Harmonic mode (HAR), M mode, Color M mode, Anatomical M mode, Color Flow Doppler(CF) Mode, Power Doppler(PD) Mode, Directional PD mode, Pulsed Wave Doppler(PWD) Mode, Continuous Wave Doppler(CWD) Mode, High PRF Doppler mode, Tissue Doppler Imaging(TDI) Mode, 3D/4D mode

2. Combination Mode:
B/Color Doppler, B/PWD, B/Color Doppler/PWD

Acoustic output track:
Track 3

Types of transducers compatible with the device :

	SC1-4HS	**SC1-4H**	**SC1-6H**	**L3-12H**	**SVC1-6H**
Transducer type	Convex	Convex	Convex	Linear	Volume Convex
Applicable frequency	1~4MHz	1~4MHz	1~6MHz	3~12MHz	1~6MHz
Intended usage	Fetal, Abdominal, Pediatric, Urology (including prostate)	Fetal, Abdominal, Pediatric, Urology (including prostate)	Fetal, Abdominal, Pediatric, Musculo-skeletal (Conventional) Musculo-skeletal (Superficial), Urology (including prostate)	Small Organ (breast, testes,thyroid), Musculo-skeletal (Conventional) Musculo-skeletal (Superficial), Peripheral vessel	Fetal, Abdominal, Pediatric, Urology (including prostate)
Applicable mode	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined/ Other
Scanning Depth (mm)	300	300	300	100	300
Total number of element	166	192	192	192	192
Predicate	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)

	EV3-10H	VE3-10H	EC3-10H	CW2.0	CW5.0
Transducer type	Endocavity	Volume Endocavity	Endocavity	Pencil Doppler	Pencil Doppler
Applicable frequency	3~10MHz	3~10MHz	3~10MHz	2.0MHz	5.0MHz
Intended usage	Fetal, Trans-rectal, Trans-vaginal, Urology (including prostate)	Fetal, Trans-rectal, Trans-vaginal, Urology (including prostate)	Fetal, Trans-rectal, Trans-vaginal, Urology (including prostate)	Cardiac Adult, Cardiac Pediatric	Cardiac Adult, Cardiac Pediatric
Applicable mode	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined/ Other	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	CWD	CWD
Scanning Depth (mm)	140	140	140	N/A	N/A
Total number of element	192	192	192	2 (TX1, RX1)	2 (TX1, RX1)
Predicate	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)	Previously cleared (K150773)

	L3-12H^{WD}	SP1-5	MP3-8
Transducer type	Linear	Sector Phased	Sector Phased
Applicable frequency	3~12MHz	1~5MHz	3~8MHz
Intended usage	Small Organ (breast, testes,thyroid), Musculo-skeletal (Conventional) Musculo-skeletal (Superficial), Peripheral vessel	Abdominal, Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric	Abdominal, Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric
Applicable mode	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/ PWD/CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined	B/M/ PWD/CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined
Scanning Depth (mm)	100	300	300
Total number of element	192	64	64
Predicate	Previously cleared (K132687)	Previously cleared (K132687)	SP3-8/SP3-8T (K132687/K153424)

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); Adult Cephalic; Trans-rectal (TR); Trans-vaginal (TV); Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Cardiac Adult; Cardiac Pediatric; Peripheral Vessel (PV); and Urology (including prostate).

Determination of Substantial Equivalence:

Comparison table with Predicate devices:

Feature	Proposed E-CUBE 11	Predicate E-CUBE 15	Predicate E-CUBE i7	Predicate E-CUBE 7
	-	K150773	K153424	K132687
Indications for Use				
- Fetal	√	√	√	√
- Abdominal (renal&GYN/pelvic)	√	√	√	√
- Pediatric	√	√	√	√
- Small Organ (breast, testes, thyroid)	√	√	√	√
- Adult Cephalic	√	√	√	
- Trans-rectal	√	√	√	√
- Trans-vaginal	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√
- Musculto skeletal (Superficial)	√	√	√	√
- Cardiac (Adult)	√	√	√	√
- Cardiac (Pediatric)	√	√	√	√
- Peripheral Vessel	√	√	√	√
- Urology (including prostate)	√	√	√	√
Imaging modes				
- 2D(B) mode	√	√	√	√
- Harmonic mode (HAR)	√	√	√	√
- M mode	√	√	√	√
- Color M mode	√		√	
- Anatomical M mode	√		√	
- Color Flow Doppler (CF) mode	√	√	√	√
- Power Doppler (PD) mode	√	√	√	√
- Directional PD mode	√		√	
- Pulsed wave Doppler (PWD) mode	√	√	√	√
- Continuous wave Doppler (CWD) mode	√	√	√	√
- High PRF Doppler mode	√		√	
- Tissue Doppler imaging (TDI) mode	√		√	
- 3D/4D mode	√	√		√
Imaging Functions				
- Xpeed™	√	√	√	√
- Full SRI™	√	√	√	√
-Spatial Compounding Image (SCI)	√	√	√	√
- Frequency	√	√		√

Compounding image (FCI)				
- Panoramic	√	√	√	√
- Stress Echo	√	√		
- Cube Strain™	√	√		
- Live HQ ™	√	√		
- Needle Vision™ / Needle Vision™ Plus	√	√	√	
- Elastography	√	√		
- Cube view™	√		√	
Thermal, mechanical and electrical safety				
- NEMA UD2, UD3	√	√	√	√
- AIUM Medical Ultrasound Safety	√	√	√	√
- IEC 60601-1	√	√	√	√
- IEC 60601-1-2	√	√	√	√
- IEC 60601-2-37	√	√	√	√

Summary of Non-Clinical Tests:

E-CUBE 11 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 11 and its application comply with voluntary standards as detailed in this premarket submission.

- IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- ISO10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- ISO14971, Application of risk management to medical devices
- AIUM Medical Ultrasound Safety
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic ultrasound Equipment

The following quality management system measures were applied to the development of E-CUBE 11:

- 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 11, did not require clinical studies to support substantial equivalence.

Discussion:
E-CUBE 11 was compared with the predicate devices. The subject device is in conformance with applicable safety standards.

Therefore, the differences between E-CUBE 11 and the predicate devices would not affect the safety, effectiveness and essential performance.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE 11 to be as safe, as effective. Performance, technology and software are substantially equivalent to the predicate devices.

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.