



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

ALPINION MEDICAL SYSTEMS Co., Ltd.  
% Mr. Donghwan Kim  
Quality Management Representative (QMR)  
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Seoul 152-848  
REPUBLIC OF KOREA

July 23, 2015

Re: K150773  
Trade/Device Name: E-CUBE 15 Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed Doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: June 19, 2015  
Received: June 22, 2015

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.

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.  
Acting 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)

K150773

Device Name

E-CUBE 15 Diagnostic Ultrasound System

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, Trans-vaginal, Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult& 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 15 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	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)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic	N	N	N	N	N	N	N	N	
Trans-rectal	P	P	P		P	P	P	P	N
Trans-vaginal	P	P	P		P	P	P	P	N
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal ( <b>Conventional</b> )	P	P	P		P	P	P	P	
Musculo-skeletal ( <b>Superficial</b> )	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	
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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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 ( <b>Conventional</b> )	P	P	P		P	P	P	P	
Musculo-skeletal ( <b>Superficial</b> )	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with SP1-5X 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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult	P	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with L8-17X 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 ( <b>Conventional</b> )	P	P	P		P	P	P	P	
Musculo-skeletal ( <b>Superficial</b> )	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with E3-10H 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									
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 ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with SVC1-6 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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with L3-12X 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 ( <i>Conventional</i> )	P	P	P		P	P	P	P	
Musculo-skeletal ( <i>Superficial</i> )	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 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	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 ( <i>Conventional</i> )	P	P	P		P	P	P	P	
Musculo-skeletal ( <i>Superficial</i> )	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric	P	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 K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use**  
**E-CUBE 15 with CW 2.0 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 ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
Intravascular									
Cardiac Adult				P					
Cardiac Pediatric				P					
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with CW 5.0 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 ( <b>Conventional</b> )									
Musculo-skeletal ( <b>Superficial</b> )									
Intravascular									
Cardiac Adult				P					
Cardiac Pediatric				P					
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K123610; E = added under appendix

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

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with C5-8 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 <i>(Conventional)</i>									
Musculo-skeletal <i>(Superficial)</i>									
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 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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with TEE3-7 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 ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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	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)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal ( <b>Conventional</b> )									
Musculo-skeletal ( <b>Superficial</b> )									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with SPN1-5X 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 <i>(Conventional)</i>									
Musculo-skeletal <i>(Superficial)</i>									
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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	N	N	N		N	N	N	N	
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									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with IO3-12 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									
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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with IO8-17 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)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal ( <b>Conventional</b> )	N	N	N		N	N	N	N	
Musculo-skeletal ( <b>Superficial</b> )	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with EV3-10X 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	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with EC3-10X 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	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 with MP1-5X 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 ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

### E-CUBE 15 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									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
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 <b>(Conventional)</b>									
Musculo-skeletal <b>(Superficial)</b>									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use

**E-CUBE 15 with C5-8N 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									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal ( <i>Conventional</i> )									
Musculo-skeletal ( <i>Superficial</i> )									
Intravascular									
Cardiac Adult									
Cardiac Pediatric	N	N	N		N	N	N	N	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
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

Prescription User (Per 21 CFR 801.109)

## Section F 510(k) Summary

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

Date March 20<sup>th</sup> 2015

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.  
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Device Trade Name: E-CUBE 15

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 15 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5" (or 19.5") wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

Modes of operation:

**1. Signal Mode:**

B(2D) mode, M mode, Color Flow(CF) mode, Power Doppler(PD) mode,  
Pulsed Wave Doppler(PWD) mode, Tissue Harmonic Imaging(THI)

**2. Combination Mode:**

B/M, B/CF, B/PD, B/PWD, B/CF/PWD, B/PD/PWD, B/CF/M

Acoustic output track:

Track 3

## Types of transducers compatible with the device:

	<b>L3-12H</b>	<b>SC1-6H</b>	<b>L8-17X</b>	<b>SP1-5X</b>
<b>Applicable frequency</b>	3~12MHz	1~6MHz	8~17MHz	1~5MHz
<b>Intended Usage</b>	Small Organ, Musculo-skeletal(conventional, superficial), Peripheral vessel	Fetal, Abdominal, Pediatric, Urology	Small Organ, Musculo-skeletal (conventional, superficial), Peripheral vessel	Abdominal, Pediatric, Cardiac Adult
<b>Foot print size (mm)</b>	44.8 x 7.8	72.4 x 16.8	58.2 x 10.4	24.8 x 17.6
<b>Applicable mode</b>	B/M/PWD/ Color Doppler/ Power Doppler	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power doppler	B/M/PWD/ CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging
<b>Scanning depth(mm)</b>	100	300	100	300
<b>FOV</b>	N/A	60(°)	N/A	90(°)
<b>Steer Angle</b>	15(°)	N/A	15(°)	45(°)
<b>Total number of element</b>	192	192	256	96
<b>Element spacing</b>	0.2mm	0.342mm	0.150mm	0.2mm
<b>elevating length</b>	4.5mm	13.5mm	4mm	13.5mm

	<b>SC1-4H</b>	<b>E3-10H</b>	<b>SVC1-6</b>	<b>L3-12X</b>
<b>Applicable frequency</b>	1~4MHz	3~10 MHz	1~6 MHz	3~12 MHz
<b>Intended Usage</b>	Fetal, Abdominal, Pediatric, Urology	Trans-rectal, Trans-vaginal	Fetal, Abdominal, Pediatric, Urology	Pediatric, Musculo-skeletal (conventional, superficial), Peripheral vessel
<b>Foot print size (mm)</b>	72.4 x 16.8	21.5 x 18.2	59.2 x 45.2	58.2 X 10.4
<b>Applicable mode</b>	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging
<b>Scanning depth(mm)</b>	300	140	300	100
<b>FOV</b>	60(°)	145(°)	79(°)	N/A
<b>Steer Angle</b>	N/A	N/A	N/A	15(°)
<b>Total number of element</b>	192	192	128	256
<b>Element spacing</b>	0.342mm	0.135mm	0.414mm	0.2mm
<b>elevating length</b>	13.5mm	6mm	13mm	4.5mm

	L3-8	SP3-8	CW2.0	CW5.0
<b>Applicable frequency</b>	3~8 MHz	3~8 MHz	2.0 MHz	5.0 MHz
<b>Intended Usage</b>	Pediatric, Musculo-skeletal (conventional, superficial), Peripheral vessel	Abdominal, Pediatric, Cardiac Pediatric,	Cardiac (Adult & Pediatric)	Cardiac (Adult & Pediatric)
<b>Foot print size (mm)</b>	44.8 x 7.8	16 x 12.8	17.2 x 17.2	11.3 x 11.3
<b>Applicable mode</b>	B/M/PWD/ Color Doppler/ Power Doppler	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	CWD	CWD
<b>Scanning depth(mm)</b>	100	300	N/A	N/A
<b>FOV</b>	N/A	90(°)	N/A	N/A
<b>Steer Angle</b>	15(°)	45(°)	N/A	N/A
<b>Total number of element</b>	128	64	2(TX1, RX1)	2(TX1, RX1)
<b>Element spacing</b>	0.3mm	0.15mm	N/A	N/A
<b>elevating length</b>	7.0mm	13.5mm	N/A	N/A

	SVC1-6H	SC1-4HS	C5-8	SPN1-5X
<b>Applicable frequency</b>	1~6 MHz	1~4 MHz	5~8 MHz	1~5MHz
<b>Intended Usage</b>	Fetal, Abdominal, Pediatric, Urology	Fetal, Abdominal, Pediatric Urology	Abdominal, Pediatric, Cardiac Pediatric	Abdominal, Pediatric, Adult Cephalic Cardiac Adult
<b>Foot print size (mm)</b>	59.2*45.2	68 x 15.9 mm	35 x 6.2 mm	24.8 x 17.6
<b>Applicable mode</b>	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging
<b>Scanning depth(mm)</b>	300	300	140	300
<b>FOV</b>	1.4mm (@65mm) 0.8mm (@105mm)	2.0mm (@65mm) 1.4mm (@105mm)	0.8mm (@65mm) 0.8mm (@105mm)	2.0mm (@65mm) 1.4mm (@105mm)
<b>Steer Angle</b>	3.7mm (@65mm) 4.5mm (@105mm)	2.8mm (@65mm) 3.9mm (@105mm)	3.9mm (@65mm) 7.0mm (@105mm)	2.68mm (@65mm) 3.9mm (@105mm)
<b>Total number of element</b>	79(°)	73(°)	92(°)	90(°)
<b>Element spacing</b>	N/A	NA	NA	45(°)
<b>elevating length</b>	Curved linear array 40mm Radius of curvature	Curved linear array 46mm Radius of curvature	Curved linear array 14mm Radius of curvature	Linear phased array

	TEE3-7	IO3-12	IO8-17	SC1-4M
<b>Applicable frequency</b>	3~7MHz	3~12MHz	8~17MHz	1~4MHz
<b>Intended Usage</b>	Cardiac (Adult)	Small Organ	Pediatric, Small Organ, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel	Fetal, Abdominal, Urology
<b>Foot print size (mm)</b>	∅ 14	22.8 x 6.4 mm	36.7 x 4.2	72.4 x 16.8
<b>Applicable mode</b>	B/M/PWD/ CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging
<b>Scanning depth(mm)</b>	140	100	100	300
<b>FOV</b>	2.0mm (@65mm) 1.4mm (@105mm)	0.3mm (@25mm) 0.5 (@45mm)	N/A	60(°)
<b>Steer Angle</b>	2.68mm (@65mm) 3.9mm (@105mm)	1.1mm (@25mm) 1.3mm (@45mm)	15(°)	N/A
<b>Total number of element</b>	90(°)	NA	128	192 X 2
<b>Element spacing</b>	45(°)	15(°)	0.200mm	0.342mm
<b>elevating length</b>	Linear phased array	Linear array 16mm aperture	3.5mm	13.5mm

	EV3-10H	EC3-10H	EV3-10X	EC3-10X
<b>Applicable frequency</b>	3-10 MHz	3-10 MHz	3-10 MHz	3-10 MHz
<b>Intended Usage</b>	Trans-rectal, Trans-vaginal, Urology	Trans-rectal, Trans-vaginal, Urology	Trans-rectal, Trans-vaginal, Urology	Trans-rectal, Trans-vaginal, Urology
<b>Foot print size (mm)</b>	21.5 x 18.6	21.5 x 18.6	21.5 x 18.6	21.5 x 18.6
<b>Applicable mode</b>	B/M/PWD/ Color Doppler/ Power Doppler			
<b>Scanning depth(mm)</b>	140	140	140	140
<b>FOV</b>	152(°)	152(°)	202(°)	202(°)
<b>Steer Angle</b>	N/A	N/A	N/A	N/A
<b>Total number of element</b>	192	192	256	256
<b>Element spacing</b>	0.14mm	0.14mm	0.14mm	0.14mm
<b>elevating length</b>	6mm	6mm	6mm	6mm

	MP1-5X	VE3-10H	C5-8N
<b>Applicable frequency</b>	1~5MHz	3-10 MHz	5~8 MHz
<b>Intended Usage</b>	Fetal, Abdominal, Pediatric, Adult Cephalic, Cardiac Adult	Trans-rectal, Trans-vaginal, Urology	Abdominal, Pediatric, Cardiac Pediatric
<b>Foot print size (mm)</b>	24.8 x 17.6	24.4 x 24.4	25.5 x 9
<b>Applicable mode</b>	B/M/PWD/CWD Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined
<b>Scanning depth(mm)</b>	300	140	140
<b>FOV</b>	90(°)	152(°)	93.6(°)
<b>Steer Angle</b>	45(°)	N/A	N/A
<b>Total number of element</b>	96	192	128
<b>Element spacing</b>	0.2mm	0.14mm	0.195mm
<b>elevating length</b>	13.5mm	6mm	6mm

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, Trans-vaginal, Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult& pediatric); Peripheral Vascular (PV); and Urology (including prostate).

Determination of Substantial Equivalence:

Comparison with Predicate device:  
1) E-CUBE 15 and E-CUBE 9

Feature	Proposed E-CUBE 15	Predicate E-CUBE 9 (K120060)
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& pediatric); Peripheral Vascular (PV); Urology (including prostate).	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); Urology (including prostate).
Electrical power	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 600 VA with Built-in and On-Board Peripherals

510(k) E-CUBE 15

Operating Mode	<p>B Mode M Mode Color Flow Mode PW Doppler Mode Power Doppler Mode Continuous wave Doppler mode Tissue Harmonic Imaging Mode 3D/4D Mode</p> <p>Xpeed™ FullSR™ Spatial Compounding Frequency Compounding Panoramic Stress Echo Cube Strain™ Live HQ™ Needle Vision™/Needle Vision™ Plus Elastography</p>	<p>B Mode M Mode Color Flow Mode PW Doppler Mode Power Doppler Mode Continuous wave Doppler mode Tissue Harmonic Imaging Mode 3D/4D Mode</p> <p>Xpeed™ FullSR™ Spatial Compounding Frequency Compounding Panoramic Stress Echo Cube Strain™ Live HQ™ Needle Vision™/Needle Vision™ Plus</p>
Thermal, mechanical and electrical safety	<p>The E-CUBE 15 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37</p>	<p>The E-CUBE 9 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37</p>

2) E-CUBE 15 and iU22

Feature	Proposed E-CUBE 15	Predicate iU 22 (K132304)
Manufacturer	Alpinion Medical System	Philips
Indications for use	<p>The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications;</p> <p>Fetal; Abdominal (renal &amp; GYN/pelvic); Pediatric, Small Organ (breast, testes, thyroid); Adult Cephalic; Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult&amp; pediatric);</p> <p>Peripheral Vascular (PV); Urology (including prostate).</p>	<p>The clinical environments where the EPIQ Diagnostic Ultrasound System can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients;</p> <p>Fetal; Abdominal Pediatric; Small Organ (breast, thyroid, testicle); Cephalic(Adult, neonatal) Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult, pediatric, fetal, trans-esophageal); Peripheral Vascular Urology Gynecological Intra-operative(vascular, cardiac) Fetal Echo Vascular (cerebral)</p>
Electrical power	<p>Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals</p>	<p>Voltage: 100~127V, 220~240V Frequency: 50/60Hz Power: 750VA~900VA</p>

Operating Mode	<p>B Mode M Mode Color Flow Mode PW Doppler Mode Power Doppler Mode Continuous wave Doppler mode Tissue Harmonic Imaging Mode 3D/4D Mode</p> <p>Xpeed™ FullSR™ Spatial Compounding Frequency Compounding Panoramic Stress Echo Cube Strain™ Live HQ™ Needle Vision™/Needle Vision™ Plus Elastography</p>	<p>M-mode Spectral Doppler Pulsed wave (PW) Doppler Auto Doppler Steerable continuous wave (CW) Doppler Tissue Doppler Imaging (TDI) Live xPlane imaging Live volume imaging/Live 3D Echo 3D/4D and MPR imaging Adaptive broadband flow imaging Contrast imaging Interventional imaging Tissue Harmonic Imaging (THI) Color Power Angio imaging (CPA) Freehand 3D volume and MPR imaging Spatio-Temporal Image Correlation (STIC) imaging Panoramic SonoCT imaging Strain based elastography Shear wave elastography</p>
Thermal, mechanical and electrical safety	<p>The E-CUBE 15 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37</p>	<p>Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the EPIQ device: - IEC60601-1 - IEC60601-1-2 - IEC60601-1-6 - IEC60601-2-37 - ISO 10993</p>

Summary of Non-Clinical Tests:

E-CUBE 15 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 15 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 15:

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

Discussion:

E-CUBE 15 and the predicate device have differences in clinical applications and operating modes. Several transducers are changed for these purposes. These design changes have been verified via non-clinical

testing. The subject device is in conformance with applicable safety standards. Therefore, the differences between E-CUBE 15 and the predicate would not affect the safety, effectiveness and essential performance of E-CUBE 15.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE 15 to be as safe, as effective. Performance, technology and software are substantially equivalent to the predicate device.

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.