



Food and Drug Administration
10903 New Hampshire Avenue
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ALPINION MEDICAL SYSTEMS Co., Ltd.
% Mr. Donghwan Kim
QARA Manager
1FL and 6FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd)
Guro-gu, Seoul 08393
REPUBLIC OF KOREA

February 26, 2016

Re: K153424
Trade/Device Name: E-CUBE i7
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 29, 2016
Received: February 1, 2016

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a large, faint, light blue watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)
K153424

Device Name
E-CUBE i7

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 i7 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	
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	N	
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 (Conventional)	N	N	N		N	N	N	N	
Musculo-skeletal (Superficial)	N	N	N		N	N	N	N	
Intravascular									
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									
Peripheral vessel	N	N	N		N	N	N	N	
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 i7 with C1-6T 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 K 142733; 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 i7 with EC3-10T 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 (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 K 142733; 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 i7 with EV3-10T 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	P	

N = new indication; P = previously cleared by FDA K 142733; 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 i7 with L3-12T 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 K 142733; 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 i7 with C5-8NT 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 (Conventional)									
Musculo-skeletal (Superficial)									
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)

Diagnostic Ultrasound Indications for Use

E-CUBE i7 with IO8-17T 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 (Conventional)	N	N	N		N	N	N	N	
Musculo-skeletal (Superficial)	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 i7 with SP1-5T 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	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	N	N	N	N	N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
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 i7 with SP3-8T 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	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	N	N	N	N	N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
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									
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)

510(k) Summary

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

Date November 23rd 2015

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.
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Seoul, 08393, Republic of Korea

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Device Trade Name: E-CUBE i7

Common/Usual Ultrasonic Pulsed Doppler Imaging System
Name:

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 K121937 E-CUBE inno Diagnostic Ultrasound System
Device

Predicate Device(s) K150773 E-CUBE 15 Diagnostic Ultrasound System
K151663 RS80A Diagnostic Ultrasound System
K142733 E-CUBE 5 Diagnostic Ultrasound System

Device Description: E-CUBE i7 product is an ultrasound imaging system for medical diagnosis. This device is available for portable(only body) and mobile(with system cart). Also, this innovative system platform provides optimal patient diagnosis workflow with the 15.6" wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

1. Signal Mode:

B(2D) mode, M mode, Color Flow(CF) mode, Power Doppler(PD) mode, Pulsed Wave Doppler(PWD) mode, Continuous wave Doppler (CWD) mode, Tissue Doppler Imaging(TDI) mode

2. Combination Mode:

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

Acoustic output track:

Track 3

Types of transducers compatible with the device:

	C1-6T	L3-12T	EC3-10T	EV3-10T
Applicable frequency	1~6MHz	3~12MHz	3~10MHz	3~10MHz
Intended Usage	Fetal, Abdominal, Pediatric, Urology	Pediatric, Small Organ, Musculoskeletal (Conventional), Musculo-skeletal (Superficial), Peripheral vessel	Trans-rectal, Trans-vaginal, Urology	Trans-rectal, Trans-vaginal, Urology
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/ Combined	B/M/PWD/ Color Doppler/ Power Doppler/ Combined
Scanning depth(mm)	300	100	100	100
FOV	60(°)	N/A	142(°)	142(°)
Steer Angle	N/A	Max 9(°)	N/A	N/A
Total number of element	128	128	128	128
Predicate	Previously cleared (K142733)	Previously cleared (K142733)	Previously cleared (K142733)	Previously cleared (K142733)

	IO8-17T	SP1-5T	SP3-8T	C5-8NT
Applicable frequency	8~17MHz	1~5MHz	3~8MHz	5~8MHz
Intended Usage	Small Organ, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial)	Abdominal, Pediatric, Adult Cephalic, Cardiac Adult	Abdominal, Pediatric, Adult Cephalic, Cardiac Adult, Cardiac Pediatric	Abdominal, Pediatric, 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	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined
Scanning depth(mm)	300	300	300	140
FOV	N/A	90(°)	90(°)	93.6(°)
Steer Angle	15(°)	45(°)	45(°)	N/A
Total number of element	128	64	64	128
Predicate	IO8-17 (K150773)	SP1-5i/SP1-5X (K121937/K150773)	SP3-8/SP1-5X (K150773/K150773)	C5-8N (K150773)

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 Vascular (PV); and Urology (including prostate).

Determination of Substantial Equivalence: Comparison with Predicate devices:
 1) E-CUBE i7 and E-CUBE inno (Primary Predicate Device)

Feature	Proposed E-CUBE i7	Predicate E-CUBE inno (K121937)
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); 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); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult); Peripheral Vascular (PV); Urology (including prostate).
Electrical power	Voltage: 19V, ---10.53A Frequency: 50/60Hz Power: 200W Max	Voltage:24V===, 6.5A Frequency: 50/60Hz Power: 120 VA MAX with Peripherals
Imaging modes	2D (B) mode M mode Anatomical M Color Flow Doppler (CF) mode Power Doppler (PD) mode Directional PD Pulsed wave Doppler (PWD) mode Continuous wave Doppler (CWD) mode Tissue Doppler imaging (TDI) mode	2D (B) mode M mode Color Flow (CF) mode Power Doppler (PD) mode Pulsed wave Doppler (PWD) mode Continuous wave Doppler (CWD) mode
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI)	Xpeed™ SRI
Software feature	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™	
Thermal, mechanical and electrical safety	The E-CUBE i7 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37	The E-CUBE inno has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37

2) E-CUBE i7 and E-CUBE 15

Feature	Proposed E-CUBE i7	Predicate E-CUBE 15 (K150773)
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 & 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); Urology (including prostate).</p>	<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 & 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); Urology (including prostate).</p>
Electrical power	<p>Voltage: 19V, \approx10.53A Frequency: 50/60Hz Power: 200W Max</p>	<p>Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals</p>
Imaging modes	<p>2D (B) Mode M Mode Anatomical M M color Mode Color Flow Doppler (CF) Mode Power Doppler (PD) Mode Directional PD Pulsed wave Doppler (PWD) Mode Continuous wave Doppler (CWD) Mode Tissue Doppler imaging (TDI) Mode</p>	<p>2D(B) Mode M Mode Color Flow Doppler (CF) Mode Power Doppler (PD) Mode Pulsed wave Doppler (PWD) Mode Continuous wave Doppler (CWD) Mode Tissue Doppler imaging (TDI) Mode Elastography 3D/4D Mode</p>
Image processing technology	<p>Xpeed™ Full SRI™ Spatial Compounding Image (SCI) High PRF Doppler</p>	<p>Xpeed™ FullSRI™ Spatial Compounding Image (SCI) Frequency Compounding Image (FCI)</p>
Software feature	<p>Panoramic Needle Vision™/Needle Vision™ Plus Cube View™</p>	<p>Panoramic Stress Echo Cube Strain™ Live HQ™ Needle Vision™/Needle Vision™ Plus</p>
Thermal, mechanical and electrical safety	<p>The E-CUBE i7 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 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>

3) E-CUBE i7 and RS80A

Feature	Proposed E-CUBE i7	Predicate RS80A (K151663)
Imaging modes	2D (B) Mode M Mode Anatomical M M color Mode Color Flow Doppler (CF) Mode Power Doppler (PD) Mode Directional PD Pulsed wave Doppler (PWD) Mode Continuous wave Doppler (CWD) Mode Tissue Doppler imaging (TDI) Mode	2D-Mode M-Mode Anatomical Mode Color M-Mode Color Doppler Power Doppler (PD) S-Flow Pulsed Wave (PW) Spectral Doppler Continuous Wave (CW) Doppler Tissue Doppler Imaging (TDI) Tissue Doppler Wave (TDW) ElastoScan Mode 3D imaging Mode 4D imaging Mode
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI) High PRF Doppler	Q scan Clearvision MultiVision HPRF
Software feature	Panoramic Needle Vision™/Needle Vision™ Plus Cube View™	Panoramic StressEcho Strain+ Needle Mate

4) E-CUBE i7 and E-CUBE 5/E-CUBE 15/E-CUBE inno

Transducer type	Proposed E-CUBE i7	Predicate E-CUBE 5 (K142733)	Predicate E-CUBE 15 (K150773)	Predicate E-CUBE inno (K121937)
Convex	C1-6T C5-8NT	C1-6T	C5-8N	
Linear	L3-12T IO8-17T	L3-12T	IO8-17	
Endocavity	EC3-10T EV3-10T	EC3-10T EV3-10T		
Sector phased	SP1-5T SP3-8T		SP1-5X	SP1-5i

Summary of Non-Clinical Tests:

E-CUBE i7 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 i7 and its application comply with voluntary standards as detailed in this premarket submission.

- ◆ 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

The following quality management system measures were applied to the development of E-CUBE i7:

- ◆ 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 i7, did not require clinical studies to support substantial equivalence.

Discussion:

E-CUBE i7 was compared with the predicate devices (K121937, K150773, K151663, and K142733)

The subject device is in conformance with applicable safety standards.

Therefore, the differences between E-CUBE i7 and the predicate devices would not affect the safety, effectiveness and essential performance.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE i7 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.