Alpinion Medical Systems Co., Ltd.
Boyeon Cho
QA/RA Manager
5fl, i dong, 77, heungan-daero 81 beon-gil dongan-gu
ANYANG-SI, GYEONGGI-DO 14117
REPUBLIC OF KOREA

January 24, 2019

Re: K182594
Trade/Device Name: E-CUBE i7
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 28, 2018
Received: December 31, 2018

Dear Boyeon Cho:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182594

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, 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 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	P	P	P		P	P	P	P	N
Abdominal	P	P	P	P	P	P	P	P	N
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P	P	P	P	P	P	N
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic	P	P	P	P	P	P	P	P	
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***)	P	P	P		P	P	P	P	
Musculo-skeletal (***Superficial***)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult	P	P	P	P	P	P	P	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	N
Urology (including prostate)	P	P	P		P	P	P	P	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 K153424; 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 K153424; 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 (***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 K153424; 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 K153424; 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	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric	P	P	P		P	P	P	P	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K153424; 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)	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									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K153424; 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	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	P	P	P	P	P	P	P	P	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult	P	P	P	P	P	P	P	P	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K153424; 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	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	P	P	P	P	P	P	P	P	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult	P	P	P	P	P	P	P	P	
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 K153424; 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 L3-12H^{WD} 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									
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 K172732; 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 L8-17H 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	N	N	N		N	N	N	N	
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 L3-8H 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	N	N	N		N	N	N	N	
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 VC1-6T 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	P
Abdominal	P	P	P		P	P	P	P	P
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	P
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	P

N = new indication; P = previously cleared by FDA K172732; 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 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 (***Conventional***)									
Musculo-skeletal (***Superficial***)									
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

Diagnostic Ultrasound Indications for Use

E-CUBE i7 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									
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 K172732; E = added under appendix

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

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Concurrence of CDRH

Diagnostic Ultrasound Indications for Use

E-CUBE i7 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									
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 K172732; E = added under appendix

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

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Concurrence of CDRH

510(k) Summary

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

Date: Jan. 04, 2019

Submitter:
ALPINION MEDICAL SYSTEMS Co., Ltd.
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Device Trade Name: E-CUBE i7

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
K153424 E-CUBE i7 Diagnostic Ultrasound System
K150773 E-CUBE 15 Diagnostic Ultrasound System
K172732 E-CUBE 8 Diagnostic Ultrasound System
K132687 E-CUBE 7 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, 3D, 4D

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
Previously cleared	K153424	K153424	K153424	K153424
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

	IO8-17T	SP1-5T	SP3-8T	C5-8NT
Previously cleared	K153424	K153424	K153424	K153424
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

	L3-12H^{WD}	L3-8H	L8-17H	IO3-12
Previously cleared	K172732	New	New	K132687
Applicable frequency	3~12MHz	3~8MHz	8~17MHz	3~12MHz
Intended Usage	Small Organ, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral	Small Organ, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral	Small Organ, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral	Small Organ

	vessel	vessel	vessel	
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
Scanning depth(mm)	100	100	100	100
FOV	N/A	N/A	NA	NA
Steer Angle	Max 9(°)	15(°)	15(°)	15(°)
Total number of element	192	166	192	80

	VC1-6T	**CW2.0**	**CW5.0**
Previously cleared	K172732	K172732	K172732
Applicable frequency	1~6MHz	2MHz	5MHz
Intended Usage	Fetal, Abdominal, Pediatric, Urology	Cardiac Adult , Cardiac Pediatric	Cardiac Adult , Cardiac Pediatric
Applicable mode	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging/ Combined/ 3D/4D	CWD	CWD
Scanning depth(mm)	300	N/A	N/A
FOV	79(°)	N/A	N/A
Steer Angle	N/A	N/A	N/A
Total number of element	128	2(TX1, RX1)	2(TX1, RX1)

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 devices:
1) E-CUBE i7 and E-CUBE i7 (Primary Predicate Device)

Feature	Proposed E-CUBE i7	Predicate E-CUBE i7 (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); 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); Adult Cephalic; Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult); Cardiac (Pediatric); Peripheral Vessel (PV); Urology (including prostate).
Electrical power	Voltage: 19V, ⎓ **10.5A** Frequency: 50/60Hz Power: 200W Max	Voltage: 19V, ⎓ 10.53A Frequency: 50/60Hz Power: 200W Max
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 **3D/4D mode**	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
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI) **ECG mode**	Xpeed™ Full SRI™ Spatial Compounding Image (SCI)
Software feature	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™ **Cube Strain™** **Stress Echo**	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 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2:2007 IEC 60601-2-37:2007+AMD1:2015 IEC61000-3-2:2014 IEC 61000-3-3:2013 IEC 61000-4-2:2008 IEC 61000-4-3:2006+A1:2007+A2:2010 IEC61000-4-4:2012	The E-CUBE i7 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2:2007 IEC 60601-2-37:2007+AMD1:2015 IEC61000-3-2:2014 IEC 61000-3-3:2013 IEC 61000-4-2:2008 IEC 61000-4-3:2006+A1:2007+A2:2010 IEC61000-4-4:2012

	IEC61000-4-5:2014 IEC61000-4-6:2013 IEC61000-4-11:2004 IEC61000-4-8:2009	IEC61000-4-5:2014 IEC61000-4-6:2013 IEC61000-4-11:2004 IEC61000-4-8:2009
option	Wireless LAN	-

2) E-CUBE i7 and E-CUBE 15

Feature	**Proposed** **E-CUBE i7**	**Predicate** **E-CUBE 15** (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 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); Adult Cephalic; Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult); Cardiac (Pediatric); Peripheral Vascular (PV); Urology (including prostate).
Electrical power	Voltage: 19V, ⎓ **10.5A** Frequency: 50/60Hz Power: 200W Max	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board 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 3D/4D mode	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 3D/4D Mode Elastography
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI) ECG mode	Xpeed™ FullSRI™ Spatial Compounding Image (SCI) ECG Mode Frequency Compounding Image (FCI)
Software feature	Panoramic Needle Vision™	Panoramic Needle Vision™

	/Needle Vision™ Plus Cube View™ Cube Strain™ Stress Echo	/Needle Vision™ Plus Cube View™ Cube Strain™ Stress Echo Live HQ™
Thermal, mechanical and electrical safety	The E-CUBE i7 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11	The E-CUBE i7 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11
option	Wireless LAN	-

3 E-CUBE i7 and E-CUBE 8

Feature	**Proposed E-CUBE i7**	**Predicate E-CUBE 8** (K172732)
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); Adult Cephalic; Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult); Cardiac (Pediatric); Peripheral Vascular (PV); Urology (including prostate). Neonatal Cephalic
Electrical power	Voltage: 19V, ⎓ **10.5A** Frequency: 50/60Hz Power: 200W Max	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: 450 VA
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 Doppler (CF) Mode Power Doppler (PD) Mode Pulsed wave Doppler (PWD) Mode Continuous wave Doppler (CWD) Mode Tissue Doppler imaging (TDI) Mode

	3D/4D mode	3D/4D Mode Elastography
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI) ECG mode	Xpeed™ FullSRI™ Spatial Compounding Image (SCI) Frequency Compounding Image (FCI)
Software feature	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™ Cube Strain™ Stress Echo	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™ Cube Strain™ Stress Echo Volume Advance™
Thermal, mechanical and electrical safety	The E-CUBE i7 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11	The E-CUBE 8 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11
option	Wireless LAN	Wireless LAN

4 E-CUBE i7 and E-CUBE 7

Feature	**Proposed** **E-CUBE i7**	**Predicate** **E-CUBE 7** (K132687)
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); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult); Cardiac (Pediatric); Peripheral Vascular (PV); Urology (including prostate).
Electrical power	Voltage: 19V, ⎓ **10.5A** Frequency: 50/60Hz Power: 200W Max	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: 600 VA
Imaging modes	2D (B) mode M mode	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 3D/4D mode	 Color Flow Doppler (CF) Mode Power Doppler (PD) Mode Pulsed wave Doppler (PWD) Mode Continuous wave Doppler (CWD) Mode 3D/4D Mode
Image processing technology	Xpeed™ Full SRI™ Spatial Compounding Image (SCI) ECG mode	Xpeed™ FullSRI™ Spatial Compounding Image (SCI) ECG Mode Frequency Compounding Image (FCI)
Software feature	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™ Cube Strain™ Stress Echo	Panoramic
Thermal, mechanical and electrical safety	The E-CUBE i7 has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11	The E-CUBE 7has been designed to conform to the following standards: NEMA UD2 AIUM Medical Ultrasound Safety IEC60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3 IEC61000-4-4 IEC61000-4-5 IEC61000-4-6 IEC61000-4-8 IEC61000-4-11
option	Wireless LAN	-

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, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- 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 (K153424, K150773). E-CUBE i7 and predicate model K153424 is difference between the ECG, 3D/4D function, several image functions.
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.