Alpinion Medical Systems Co., Ltd.
℅ Boyeon Cho
Quality Management Representative
5FL, I dong, 77, heungan-daero 81 beon-gil dongan-gu
Anyang-si, Gyeonggi-do 14117
REPUBLIC OF KOREA

January 28, 2022

Re: K213523
Trade/Device Name: X-CUBE i8, X-CUBE i9
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 1, 2021
Received: November 3, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213523

Device Name
X-CUBE i8, X-CUBE i9

Indications for Use *(Describe)*
The X-CUBE i8, X-CUBE i9 diagnostic ultrasound systems are intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for the evaluation of soft tissue and blood flow in the clinical applications of Fetal; Abdominal(renal & GYN/pelvic); Pediatric; Small Organ(breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional); Musculo-skeletal(Superficial); Cardiac(adult& pediatric); Trans-esoph. (Cardiac); Peripheral Vessel(PV); and Urology(including prostate).

And, in the imaging modes of 2D(B) mode; Harmonic mode(HAR); M mode; Color M mode; Anatomical M mode; Color Flow Doppler(CF) Mode; Power Doppler(PD) Mode; Directional PD mode; Pulsed Wave Doppler(PWD) Mode; Continuous Wave Doppler(CWD) Mode; High PRF Doppler mode; Tissue Doppler Imaging(TDI) Mode.

The X-CUBE i8, X-CUBE i9 are intended to be used in a hospital or medical clinic.

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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K213523

510(k) Summary

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

Date	Nov 4st, 2021
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 5FL, I dong, 77, heungan-daero 81 beon-gil dongan-gu Anyang-si, Gyeonggi-do, 14117, REPUBLIC OF KOREA
Primary Contact Person	Boyeon CHO Quality Management Representative(QMR) Address: 5FL, I dong, 77, heungan-daero 81 beon-gil dongan-gu Anyang-si, Gyeonggi-do, 14117, REPUBLIC OF KOREA Phone: +82 70 7465 2104 Fax: +82 2 851 5595 Email: qa_ra@alpinion.com
Secondary Contact Person	Kevin CHUN Address: 21222 30th Dr SE Ste C-122, Bothell, WA 98021, United States Phone: 425 949 1059 Fax: 425 949 4910 Email: kevin.chun@alpinionusa.com
Device Trade Name:	X-CUBE i8, X-CUBE i9
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	K182594 E-CUBE i7 Ultrasonic Pulsed Doppler Imaging System
Reference Devices	K211300 X-CUBE 90 Ultrasonic Pulsed Doppler Imaging System K181277 E-CUBE 12 Ultrasonic Pulsed Doppler Imaging System K150773 E-CUBE 15 Ultrasonic Pulsed Doppler Imaging System K181617 E-CUBE 8 Ultrasonic Pulsed Doppler Imaging System K161439 E-CUBE 11 Ultrasonic Pulsed Doppler Imaging System
Subject device New technology	The new technology of the subject device is as follows compared to Predicate and Reference devices. 1. Transducer C1-7GT

2. Feature
Please see comparison table on pages F-3 to F-6

Device Description:

X-CUBE i8 and X-CUBE i9 products are an ultrasound imaging system for medical diagnosis. This system platform provides optimal patient diagnosis workflow with the wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

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

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

Acoustic output track:
Track 3

Indications For Use:

The X-CUBE i8, X-CUBE i9 diagnostic ultrasound systems are intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for the evaluation of soft tissue and blood flow in the clinical applications of Fetal; Abdominal(renal & GYN/pelvic); Pediatric; Small Organ(breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-vaginal; Musculo-skeletal(Conventional); Musculo-skeletal(Superficial); Cardiac(adult& pediatric); Trans-esoph. (Cardiac); Peripheral Vessel(PV); and Urology(including prostate).

And, in the imaging modes of 2D(B) mode; Harmonic mode(HAR); M mode; Color M mode; Anatomical M mode; Color Flow Doppler(CF) Mode; Power Doppler(PD) Mode; Directional PD mode; Pulsed Wave Doppler(PWD) Mode; Continuous Wave Doppler(CWD) Mode; High PRF Doppler mode; Tissue Doppler Imaging(TDI) Mode.

The X-CUBE i8, X-CUBE i9 are intended to be used in a hospital or medical clinic.

Determination of Substantial Equivalence: Comparison table with Predicate devices:

Model / Feature	**Proposed X-CUBE i8, X-CUBE i9** ALPINION Medical Systems Co., Ltd.	**Predicate E-CUBE i7** ALPINION Medical Systems Co., Ltd.	**Reference X-CUBE 90** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 12** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 15** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 8** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 11** ALPINION Medical Systems Co., Ltd.
	K213523	**K182594**	**K211300**	**K181277**	**K150773**	**K181617**	**K161439**
	Indications for Use						
- Fetal	√	√	√	√	√	√	√
- Abdominal (Renal&GYN/Pelvic)	√	√	√	√	√	√	√
- Intra-operative (Specify, Neuro)							
- Pediatric	√	√	√	√	√	√	√
- Small Organ (breast, testes, thyroid)	√	√	√	√	√	√	√
- Neonatal Cephalic	√		√	√		√	
- Adult Cephalic	√	√	√	√	√	√	√
- Trans-rectal	√	√	√	√	√	√	√
- Trans-vaginal	√	√	√	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√	√	√	√
- Musculto skeletal (Superficial)	√	√	√	√	√	√	√
- Cardiac (Adult)	√	√	√	√	√	√	√
- Cardiac (Pediatric)	√	√	√	√	√	√	√
- Trans-esoph. (Cardiac)	√						
- Peripheral Vessel	√	√	√	√	√	√	√
- Urology (including prostate)	√	√	√	√	√	√	√
	Dimensions and Weight						
Weight (Excluding options)	6kg (excluding Option)	7.2kg (excluding Option)	85kg	94 kg	105 kg	55 kg	94 kg
Height	62.5/352 mm	84.9 mm	1325/1560 mm	1,420/1,520 mm	1,413/1,848 mm	830~1,430 mm	1,455/1,695 mm

Width	385 mm	402.6 mm	554 mm	590 mm	585 mm	532 mm	590 mm
Depth	370 mm	366.5 mm	815 mm	895 mm	670 mm	787 mm	895 mm
	Electrical Power						
Voltage	20V⎓, 11A	19V⎓, 10.5A	100-120V~, 200-240V~	100-120V~, 200-240V~	100-120V~, 200-240V~	100-120V~, 200-240V~	100-120V~, 200-240V~
Frequency	50-60 Hz	50-60 Hz	50-60 Hz	50/60 Hz	50-60 Hz	50-60 Hz	50/60 Hz
Power	Max. 220W	Max. 200W	Max. 700VA	Max. 600VA	Max. 900VA	Max. 450VA	Max. 600VA
	Imaging Modes						
- 2D(B) mode	√	√	√	√	√	√	√
- Harmonic mode	√	√	√	√		√	√
- M mode	√	√	√	√	√	√	√
- Color M mode	√	√	√	√		√	√
- Anatomical M mode	√	√	√	√		√	√
- Color Flow Doppler (CF) mode	√	√	√	√	√	√	√
- Power Doppler (PD) mode	√	√	√	√	√	√	√
- Directional PD mode	√	√	√	√		√	√
- Pulsed wave Doppler (PWD) mode	√	√	√	√	√	√	√
- Continuous wave Doppler (CWD) mode	√	√	√	√	√	√	√
- High PRF Doppler mode	√	√	√	√		√	√
- Tissue Doppler imaging (TDI) mode	√	√	√	√	√	√	√
	Features						
- Xpeed™	√	√	√	√	√	√	√
- Full SRI™	√	√	√	√	√	√	√
-Spatial Compounding Image (SCI)	√	√	√	√	√	√	√
- Panoramic	√	√	√	√	√	√	√

- Stress Echo	√	√	√	√	√	√	√
- Cube Strain™	√	√	√	√	√	√	√
- Needle Vision™ Plus	√	√	√	√	√	√	√
- Elastography	√		√	√	√	√	√
- Cube view™	√	√	√	√	√	√	√
- Contrast Enhanced Ultrasound (CEUS)	√		√	√	√	√	
- Cube Note	√		√	√	√		
- Auto EF	√		√				
- Auto NT	√		√	√		√	√
- Microvascular Imaging (MVI)	√		√				
	Accessories or Kits						
Color printer	√	√	√	√	√	√	√
B/W printer	√	√	√	√	√	√	√
DVD-RW	√	√	√	√	√	√	√
Foot switch	√	√	√	√	√	√	√
Wireless LAN	√	√	√	√		√	√
SC1-6 Biopsy guide kit	√	√	√	√	√	√	√
L3-12 Biopsy guide kit	√	√	√	√	√	√	√
EN3-10 Reusable Biopsy needle guide	√	√		√	√	√	√
EN3-10 Disposable Biopsy needle guide	√	√		√	√	√	√
ECG module / cable	√	√	√	√	√	√	√
	Disinfectant & Ultrasound Gel						
Ultrasonic gel	√	√	√	√	√	√	√
Cidex OPA (Disinfectant agaents)	√	√	√	√	√	√	√

Cidex Plus (Disinfectant agaents)	√	√	√	√	√	√	√
Gigasept FF (Disinfectant agaents)	√	√	√	√	√	√	√
Virkon (Disinfectant agaents)	√	√	√	√	√	√	√
Wavicide-01 (Disinfectant agaents)	√	√	√	√	√	√	√
AIDAL PLUS (Disinfectant agaents)	√	√	√	√	√	√	√
Cetylcide-G (Disinfectant agaents)	√	√	√	√	√	√	√
Sporicidin (Disinfectant agaents)	√	√	√	√	√	√	√
	Thermal, mechanical and electrical safety						
- NEMA UD2, UD3	√	√	√	√	√	√	√
- AIUM Medical Ultrasound Safety	√	√	√	√	√	√	√
- IEC 60601-1	√	√	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√	√	√
- IEC 60601-2-37	√	√	√	√	√	√	√

Summary of Non-Clinical Tests:

X-CUBE i8 and X-CUBE i9 have 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. X-CUBE i8, X-CUBE i9 and its application comply with voluntary standards as detailed in this premarket submission.

- IEC60601-1:2005(Third Edition)+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC60601-2-37:2007/AMD1:2015, Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- AAMI/ANSI/ISO10993-1:2009(R)2013, Biological Evaluation of Medical Devices - Part 1:Evaluation and Testing within a risk management process
- AAMI/ANSI/ISO14971:2007/(R)2010, Medical devices-Application of risk management to medical devices
- AIUM MUS, Third edition, Medical Ultrasound Safety
- NEMA UD 2-2004(R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3-2004(R2009), Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic ultrasound Equipment

The following quality management system measures were applied to the development of X-CUBE i8 and X-CUBE i9:

- 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, X-CUBE i8 and X-CUBE i9, did not require clinical studies to support substantial equivalence.

Discussion:
X-CUBE i8 and X-CUBE i9 were compared with the predicate device. The subject devices are in conformance with applicable safety standards.

Therefore, the differences between X-CUBE i8 and X-CUBE i9, and the predicate device would not affect the safety, effectiveness and essential performance.

Conclusion: The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The devices are designed to conform to applicable medical device safety standards and compliance.
Therefore, ALPINION MEDICAL SYSTEMS Co., Ltd. considers X-CUBE i8 and X-CUBE i9 to be as safe, and effective as the predicate device.