Alpinion Medical Systems Co., Ltd.
Boyeon Cho
Quality Management Representative
1FL and 6FL, Verdi Tower, 72, Digital-ro 26-gil, Guro-gu
SEOUL, 0839
SOUTH KOREA

September 28, 2018

Re: K181277
Trade/Device Name: E-CUBE 12
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 23, 2018
Received: August 27, 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); 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.

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)*
K181277

Device Name
E-CUBE 12

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), Neonatal Cephalic, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date	May 9th, 2018
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1FL and 6FL, Verdi Tower, 72, Digital-ro 26-gil, Guro-gu, Seoul, Republic of Korea
Primary Contact Person	Boyeon CHO Quality Management Representative(QMR) Address: 1FL and 6FL, Verdi Tower, 72, Digital-ro 26-gil, Guro-gu, Seoul, Republic of Korea Phone: +82 70 7465 2104 Fax: +82 2 851 5595 Email: qa_ra@alpinion.com
Secondary Contact Person	JULIAN LEE Address: 21312 30th Dr SE Ste 100 Bothell, WA 98021, United States Phone: 425 949 1059 Fax: 425 949 4910 Email: julian.lee@alpinionusa.com
Device Trade Name:	E-CUBE 12
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	K172732 E-CUBE 8 Diagnostic Ultrasound System
Predicate Devices	K161439 E-CUBE 11 Diagnostic Ultrasound System K150773 E-CUBE 15 Diagnostic Ultrasound System K173713 HS70A Diagnostic Ultrasound System
Device Description:	E-CUBE 12 product is an ultrasound imaging system for medical diagnosis. This innovative system platform provides optimal patient diagnosis workflow with the wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

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

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

Acoustic output track:
Track 3

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

Determination of Substantial Equivalence: Comparison table with Predicate devices:

Model / Feature	Proposed E-CUBE 12 ALPINION Medical Systems Co., Ltd.	Predicate E-CUBE 8 ALPINION Medical Systems Co., Ltd.	Predicate E-CUBE 11 ALPINION Medical Systems Co., Ltd.	Predicate E-CUBE 15 ALPINION Medical Systems Co., Ltd.	Predicate HS70A Samsung Medison co., ltd
	-	K172732	K161439	K150773	K173713
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)	√	√	√	√	√
- Peripheral Vessel	√	√	√	√	√
- Urology (including prostate)	√	√	√	√	√

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	√	√	√	√	√
- 3D/4D mode	√	√	√	√	√
Imaging Functions					
- Xpeed™	√	√	√	√	√
- Full SRI™	√	√	√	√	√
-Spatial Compounding Image (SCI)	√	√	√	√	√
- Frequency Compounding image(FCI)	√	√	√	√	√
- Panoramic	√	√	√	√	√
- Stress Echo	√	√	√	√	√
- Cube Strain™	√	√	√	√	√

- Live HQ ™	√	√	√	√	√
- Needle Vision™ / Needle Vision™ Plus	√	√	√	√	√
- Elastography	√	√	√	√	√
- Cube view™	√	√	√		
- Volume Advance™					
• Free Angle MSV	√	√			√
• AnySlice™	√	√			√
• Volume Analysis	√	√			√
Thermal, mechanical and electrical safety					
- NEMA UD2, UD3	√	√	√	√	√
- AIUM Medical Ultrasound Safety	√	√	√	√	√
- IEC 60601-1	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√
- IEC 60601-2-37	√	√	√	√	√

Summary of Non-Clinical Tests:

E-CUBE 12 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 12 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 Edition 3:2007-03, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC60601-2-37 Edition 2.0:2007, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- AAMI/ANSI/ISO10993-1:2009(R)2013, Biological Evaluation of Medical Devices - Part 1:Evaluation and Testing
- 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 E-CUBE 12:

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

Discussion:
E-CUBE 12 was compared with the predicate devices. The subject device is in conformance with applicable safety standards.

Therefore, the differences between E-CUBE 12 and the predicate devices would not affect the safety, effectiveness and essential performance.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE 12 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.