April 17, 2023

Alpinion Medical Systems Co., Ltd.
℅ Boyeon CHO
Quality Management Representative
4F, 15, Magokjungang 14-ro, Gangseo-gu
Seoul, Seoul 07789
KOREA

Re: K223564
Trade/Device Name: X-CUBE 50, X-CUBE 60
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 24, 2023
Received: March 27, 2023

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K223564

Device Name
X-CUBE 50, X-CUBE 60

Indications for Use *(Describe)*
The X-CUBE 50, X-CUBE 60 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); 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(Pulse Repetition Frequency) Doppler mode; Tissue Doppler Imaging(TDI) Mode; 3D/4D mode.

The X-CUBE 50, X-CUBE 60 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.

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

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510(k) Summary

K223564

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

Date	Mar 24th, 2023
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea
Primary Contact Person	Boyeon CHO Quality Management Representative(QMR) Address: 4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea Phone: +82.2.3777.8600 Fax: +82.2.3777.8691 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 50, X-CUBE 60
Common/ Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Names	System, Imaging, Pulsed Doppler Ultrasonic
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX
Predicate Device	K220857 X-CUBE 50, X-CUBE 60 Ultrasonic Pulsed Doppler Imaging System
Reference Devices	K221093 X-CUBE 70, X-CUBE 90 Ultrasonic Pulsed Doppler Imaging System
Proposed New Device	The new device are as follows compared to the cleared Predicate devices. - X-CUBE 50 Change model name: C1-7GT → C1-6C, Add model: C1-6CT - X-CUBE 60 Add models: L10-25H, SL3-19X, C1-6CT, C1-6C - Add accessories: EC2-11H/EV2-11H Disposable Biopsy needle guide
Device Description:	The X-CUBE 50 and X-CUBE 60 products are general purpose ultrasound imaging system for medical diagnosis assistance. These products are used as an aid tool to diagnosis, such as a commonly used

ultrasound diagnostic device.
Also X-CUBE 50 and X-CUBE 60 have the same operating principles, intended use, risk grade and design/manufacturing characteristics as reference/predicate devices.

This systems platform provide patient diagnosis workflow with the wide flat panel display, ergonomic control panel with easy user interface, image quality.

1. Patient population
Adult and Pediatric

2. 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(Pulse Repetition Frequency) Doppler mode, Tissue Doppler Imaging(TDI) Mode, 3D/4D mode

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

4. Acoustic output track:
Track 3

Indications For Use:

The X-CUBE 50, X-CUBE 60 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); 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(Pulse Repetition Frequency) Doppler mode; Tissue Doppler Imaging(TDI) Mode; 3D/4D mode.

The X-CUBE 50, X-CUBE 60 are intended to be used in a hospital or medical clinic.

Differences between Proposed Devices.

The difference between the X-CUBE 50 and X-CUBE 60 is the number of Tx/Rx channels. X-CUBE 50 operates with 64 channels, but X-CUBE 60 operates with 128 channels. The component constituting the Tx/Rx channel is the FE(Front End) board. Both devices are in the same except for the FE(Front End) board.

Determination of Substantial Equivalence: Comparison table with Predicate devices:

Feature \ Model	**Proposed X-CUBE 50, X-CUBE 60** ALPINION Medical Systems Co., Ltd.	**Predicate X-CUBE 50, X-CUBE 60** ALPINION Medical Systems Co., Ltd.	**Reference X-CUBE 70, X-CUBE 90** ALPINION Medical Systems Co., Ltd.
	K223564	**K220857**	**K221093**
	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)	√	√	√
	Dimensions and Weight		
Weight (Excluding options)	70kg	70kg	85kg
Height	1310/1670mm	1310/1670mm	1,440/1,605 mm
Width	560mm	560mm	580 mm
Depth	780mm	780mm	835 mm
	Electrical Power		
Voltage	100-120V~, 200-240V~	100-120V~, 200-240V~	100-120V~, 200-240V~
Frequency	50-60 Hz	50-60 Hz	50-60 Hz
Power	Max. 600VA	Max. 600VA	Max. 700VA
	Imaging Modes		
- 2D(B) mode	√	√	√
- Harmonic mode	√	√	√

- M mode	√	√	√
- Color M mode	√	√	√
- Anatomical M mode	√	√	√
- Color Flow Doppler (CF) mode	√	√	√
- Power Doppler (PD) mode	√	√	√
- Microvascular Imaging (MVI)	√	√	√
- Directional PD mode	√	√	√
- Pulsed wave Doppler (PWD) mode	√	√	√
- Continuous wave Doppler (CWD) mode	√	√	√
- High PRF(Pulse Repetition Frequency) Doppler mode	√	√	√
- Tissue Doppler imaging (TDI) mode	√	√	√
- 3D/4D mode	√	√	√
	Imaging Features		
- Xpeed™	√	√	√
- Full SRI™	√	√	√
-Spatial Compounding Image (SCI)	√	√	√
- Panoramic	√	√	√
- Stress Echo	√	√	√
- Cube Strain™	√	√	√
- Live HQ™	√	√	√
- Needle Vision™/ Needle Vision™ Plus	√	√	√
- Elastography	√	√	√
- Cube view™	√	√	√
- Contrast Enhanced Ultrasound (CEUS)	√	√	√
- Cube Note	√	√	√
- B-STIC(STIC)	√	√	√
- Auto EF	√	√	√
- AnySlice™	√	√	√
- X + Compare	√	√	√
- X + Assistant	√	√	√
- Time Intensity Curve (TIC) Analysis	√	√	√
- Auto NT Measurements	√	√	√

- X + Auto Biometry	√	√	√
- Auto IMT Measurements	√	√	√
	Accessories or Kits		
Color printer	√	√	√
B/W printer	√	√	√
DVD-RW	√	√	√
Foot switch	√	√	√
Wireless LAN	√	√	√
SC1-6 Biopsy guide kit	√	√	√
L3-12 Biopsy guide kit	√	√	√
L3-12X Biopsy guide kit	√	√	√
EV2-11H Reusable Biopsy needle guide	√	√	√
EC2-11H/EV2-11H Disposable Biopsy needle guide	√		
EN3-10 Reusable Biopsy needle guide	√	√	
EN3-10 Disposable Biopsy needle guide	√	√	
VE3-10H Reusable Biopsy needle guide	√	√	√
VE3-10H 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	√	√	√
	Transducer Comparison (related to K223564)		
C1-6C	√	√	
C1-6CT	√		
L10-25H	√		√
SL3-19X	√		√
	- For C1-6C, only the model name has been changed from C1-7GT(K220857). - C1-6CT is the new model. However, except for the slight difference in Applicable frequency, C1-6CT and C1-6C are the same Convex type probe and provide the same applicable mode, indications for use, element size, element spacing. - L10-25H and SL3-19X are the same transducers as the predicate device(K221093).		

Summary of Non-Clinical Tests:

X-CUBE 50 and X-CUBE 60 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 50, X-CUBE 60 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 50 and X-CUBE 60:

- 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 50 and X-CUBE 60, did not require clinical studies to support substantial equivalence.

Discussion:
X-CUBE 50 and X-CUBE 60 were compared with the predicate device. The subject devices are in conformance with applicable safety standards.

Therefore, the differences between X-CUBE 50 and X-CUBE 60, 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 50 and X-CUBE 60 to be as safe, and effective as the predicate device.