October 14, 2022

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

Re: K221093
Trade/Device Name: X-cube 70, X-cube 90
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 13, 2022
Received: September 13, 2022

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 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)*

K221093

Device Name
X-CUBE 70, X-CUBE 90

Indications for Use *(Describe)*

The X-CUBE 70 and X-CUBE 90 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, the imaging modes are 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.

The X-CUBE 70 and X-CUBE 90 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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510(k) Summary

K221093

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

Date	April 6th, 2022
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 70, X-CUBE 90
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	K211299 X-CUBE 70 Diagnostic Ultrasound System K211300 X-CUBE 90 Diagnostic Ultrasound System
Reference Devices	K181277 E-CUBE 12 Diagnostic Ultrasound System K181617 E-CUBE 8 Diagnostic Ultrasound System K161439 E-CUBE 11 Diagnostic Ultrasound System
Proposed Device New Technology	The new technology of the subject device is as follows compared to the cleared Predicate and Reference devices. 1. Diagnostic Feature Attenuation Imaging (ATI) 2D Shear Wave Elastography (2D SWE) Radiant View (Brilliant flow) Color STIC

3D color

* Please refer to page F-8 for Technological Characteristics of The new diagnostic features.

Device Description:

The X-CUBE 70 and X-CUBE 90 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 70 and X-CUBE 90 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 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 70 and X-CUBE 90 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, the imaging modes are 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.

The X-CUBE 70 and X-CUBE 90 are intended to be used in a hospital or medical clinic.

Differences between Proposed Devices.

The difference between the X-CUBE 90 and X-CUBE 70 is the number of Tx/Rx channels. X-CUBE 90 operates with 192 channels, but X-CUBE 70 operates with 128 channels. The component constituting the Tx/Rx channel is the FE board. Both devices are in the same except for the FE board.

Determination of Substantial Equivalence: Comparison table with Predicate devices:

Feature \ Model	**Proposed X-CUBE 70, X-CUBE 90** ALPINION Medical Systems Co., Ltd.	**Primary Predicate X-CUBE 70** ALPINION Medical Systems Co., Ltd.	**Secondary Predicate X-CUBE 90** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 12** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 8** ALPINION Medical Systems Co., Ltd.	**Reference E-CUBE 11** ALPINION Medical Systems Co., Ltd.
	K221093	**K211299**	**K211300**	**K181277**	**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)	85kg	90kg	85kg	94 kg	55 kg	94 kg

Height	1,440/1,605 mm	1,325/1,560 mm	1,325/1,560 mm	1,420/1,520 mm	830~1,430 mm	1,455/1,695 mm
Width	580 mm	554 mm	554 mm	590 mm	532 mm	590 mm
Depth	835 mm	815 mm	815 mm	895 mm	787 mm	895 mm
	Electrical Power					
Voltage	100-120V~, 200-240V~	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
Power	Max. 700VA	Max. 700VA	Max. 700VA	Max. 600VA	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	√	√	√	√	√	√
- Microvascular Imaging (MVI)	√	√	√			
- 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™	√	√	√	√	√	√
- Contrast Enhanced Ultrasound (CEUS)	√	√	√	√	√	
- Cube Note	√	√	√	√		
- B-STIC	√	√	√	√		
- Auto EF	√	√	√			
- Point Shear Wave Elastography (PSWE)	√	√	√			
- Attenuation Imaging (ATI)	√					
- 2D Shear Wave Elastography (2D SWE)	√					
- Radiant View (Brilliant flow)	√					
- Color STIC	√					
- 3D color	√					
	Volume Advance™					
• Free Angle MSV	√	√	√	√	√	
• AnySlice™	√	√	√	√	√	
• Volume Analysis	√	√	√	√	√	

	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	√	√	√			
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)	√	√	√	√	√	√
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	√	√	√	√	√	√

Technological Characteristics of New Diagnostic Feature

◆ Attenuation Imaging (ATI)

Attenuation imaging is a feature that provides attenuation information of human tissue. Attenuation imaging may be used as an aid in diagnosis and monitoring patients using the attenuation coefficient of ultrasound propagation

◆ 2D Shear Wave Elastography (2D SWE)

2D Shear Wave Elastography (2D SWE) is a feature that provides elasticity information of human tissue. 2D SWE may be used as an aid in diagnosis and monitoring patients using the shear wave propagation

◆ Radiant View (Brilliant Flow)

Radiant View (Brilliant Flow) is the feature that provides 3D-like appearance in Color images. This feature makes it easy to understand the structure of blood flow and blood vessels.

◆ 3D color

3D Color imaging modes are useful for imaging structures that cannot be obtained in 2D color mode for better understanding of complex structures.

◆ Color STIC

Color STIC (Spatial Temporal Image Correlation) can visualize the heart and vascularity of a fetus in 3D B + CF mode. This acquisition method is designed for beating (fetal heart) as well as blood perfused organs.

Summary of Non-Clinical Tests:

X-CUBE 70 and X-CUBE 90 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 70, X-CUBE 90 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 70 and X-CUBE 90:

- 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 70 and X-CUBE 90, did not require clinical studies to support substantial equivalence.

Discussion:
X-CUBE 70 and X-CUBE 90 were compared with the predicate device. The subject device is in conformance with applicable safety standards.

Therefore, the differences between X-CUBE 70 and X-CUBE 90 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 70 and X-CUBE 90 to be as safe, and effective as the predicate device.