Alpinion Medical Systems Co., Ltd.
Boyeon CHO
QARA Manager
5fl, i dong, 77, heungan-daero 81 beon-gil dongan-gu
Anyang-si, Gyeonggi-do, 14117
REPUBLIC OF KOREA

December 27, 2018

Re: K182845
Trade/Device Name: minisono
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 30, 2018
Received: December 3, 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,

Michael D. O'Hara 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)*

K182845

Device Name
minisono

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; Pediatric, Small Organ (breast, testes, thyroid); Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); 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."

Diagnostic Ultrasound Indications for Use

minisono Ultrasound Imaging System: minisono C1-6

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	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)									
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	N	N		N	N	N	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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

minisono Ultrasound Imaging System: minisono L3-12

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	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

510(k) Summary

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

Date	Oct. 5th, 2018
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 5fl, i dong ,77, heungan-daero 81beon-gil, dongan-gu, anyang-si, gyeonggi-do , REPUBLIC OF KOREA, 14117
Primary Contact Person	Boyeon CHO Quality Management Representative(QMR) Address: 5fl, i dong ,77, heungan-daero 81beon-gil, dongan-gu, anyang-si, gyeonggi-do , REPUBLIC OF KOREA, 14117 Phone: +82 70 7465 2104 Fax: +82 2 851 5593 Email: qa_ra@alpinion.com
Secondary Contact Person	Kevin Chun Address: 21312 30th Dr SE Ste 100 Bothell, WA 98021, United States Phone: 425 949 4904 Fax: 425 949 4910 Email: kevin.chun@alpinionusa.com
Device Trade Name:	minisono
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
Device Description:	minisono product is an ultrasound imaging system for medical diagnosis. This device is available for portable and tablet PC (Microsoft corp., Surface pro). Also, this innovative system platform provides optimal patient diagnosis workflow with the tablet PC, optimal image quality. **1. Signal Mode**: B(2D) mode, M mode, Pulsed Wave Doppler(PWD) mode, Color Doppler, Power Doppler, Tissue Harmonic Imaging **2. Combination Mode:** B/Color Doppler, B/PWD, B/Color Doppler/PWD Acoustic output track: Track 3

Types of transducers compatible with the device:

	minisono C1-6	**minisono L3-12**
Applicable frequency	1~6MHz	3~12MHz
Intended Usage	Fetal, Abdominal, Pediatric, Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel Urology (including prostate)	Abdominal Pediatric Small Organ Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel
Applicable mode	B mode, M mode, PWD mode, Color Doppler Power Doppler Tissue Harmonic Imaging Combined	B mode, M mode, PWD mode, Color Doppler Power Doppler Tissue Harmonic Imaging Combined
Scanning depth(mm)	300	100
FOV	60(°)	N/A
Steer Angle	N/A	Max 9(°)
Total number of element	128	128

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; Pediatric, Small Organ (breast, testes, thyroid); Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Peripheral Vascular (PV); and Urology (including prostate).

Determination of Substantial Equivalence: Comparison with Predicate devices:
: minisono and E-CUBE i7

Feature	**Proposed minisono**	**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; Pediatric; Small Organ (breast, testes, thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial);	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; Pediatric; Small Organ (breast, testes, thyroid); Adult Cephalic; Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (Adult);

	Peripheral Vessel (PV); Urology (including prostate).	Cardiac (Pediatric); Peripheral Vessel (PV); Urology (including prostate).
Electrical power	Voltage: 5Vdc, ⎓1A	Voltage: 19V, ⎓10.53A Frequency: 50/60Hz Power: 200W Max
Imaging modes	2D (B) mode M mode Color Flow Doppler (CF) mode Power Doppler (PD) mode Pulsed wave Doppler (PWD) mode Tissue Harmonic Imaging 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 Harmonic Imaging mode
Image processing technology	Xpeed™ SRI™ Spatial Compounding Image (SCI)	Xpeed™ Full SRI™ Spatial Compounding Image (SCI)
Software feature	Needle Vision™ Plus	Panoramic Needle Vision™ /Needle Vision™ Plus Cube View™
Thermal, mechanical and electrical safety	The minisono has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37	The E-CUBE i7 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37

Summary of Non-Clinical Tests:

minisono 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. minisono and its application comply with voluntary standards as detailed in this premarket submission.

- IEC 60601-1:2005+AMD1:2012 (3.1ed, 2012-08-20 published), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2014 (4.0ed, 2014-02-25 published), Medical Electrical Equipment – Part 1-2:
  General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC 60601-1-6:2010+AMD1:2013(3.0ed, 2013-10-28), Medical

electrical equipment - Part 1-6: General requirements forbasic safety and essential performance - Collateral standard: Usability

- IEC60601-2-37:2007(2.0ed, 2007-08-09 published), Medical Electrical Equipment – Part 2-37:
  Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- ISO10993-1:2009(5.0ed, 2018-08 published), Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- ISO 10993-5:2009(3.0ed, 2009-06 published), Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010(3.0ed, 2010-08 published), Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ISO14971:2007(2.0ed, 2007-03 published), Application of risk management to medical devices
- AIUM/NEMA UD 2:2004 (R2009) Rev.3, 2009-08-21 published, 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 minisono:

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

Discussion:
minisono is a new device and simple diagnostic device. minisono (minisono C1-6 & minisono L3-12) are composed system and USB cable. Software is installed to the tablet PC (Microsoft corp., Surface pro). minisono's functions of imaging/software are same as predicate E-CUBE i7 functions.

Also, the subject device is in conformance with applicable safety standards.

Therefore, the differences between minisono and the predicate devices would not affect the safety, effectiveness and essential performance.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers minisono 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.