October 11, 2022

Bionet Co., Ltd.
% ChuelWon Lee
RA Manager
5F, 61 Digital-ro 31-gil Guro-gu
Seoul, 08375
REPUBLIC OF KOREA

Re: K220169
Trade/Device Name: SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SonoFinder Wireless Probe Type Ultrasound Scanner (Model: SF14L25)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 19, 2022
Received: September 20, 2022

Dear ChuelWon Lee:

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
DHT 8C: 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)*
K220169

Device Name
SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25)

Indications for Use *(Describe)*
SonoMe and SONOFINDER are indicated for examining the adult, pregnant woman, and children. These products are intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/ obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral vessel imaging.
The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.

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 K220169

In accordance with 21 CFR 807.92 the following summary of information is provided.

1. Submitter

Submitter: Bionet Co., LTD
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Connect: Primary Contact Person Name: ChuelWon Lee
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Date Prepared: January 17, 2022

2. Proposed Device

Device Name	Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L)
Trade Name	SonoMe
Regulation Number	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570
Regulation Name	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer
Product Code	IYN, IYO, ITX
Regulatory Class	Class II

Device Name	Wireless Probe Type Ultrasound Scanner (Model: SF14L25)
Trade Name	SONOFINDER
Regulation Number	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570
Regulation Name	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer
Product Code	IYN, IYO, ITX
Regulatory Class	Class II

3. Predicate Device

Type	Proposed Device	Predicate Device:
Convex	Model: 5C, 5CB, H5C	Wireless Probe Type Ultrasound Scanner / Model: UProbe-C (K172750) SONON Ultrasound Imaging System / Model: SONON 300C (K151339) C5 Diagnostic Ultrasound System (K171926)
Linear	Model: 10L, 14L, 10LB, H10L, SF14L25	Wireless Probe Type Ultrasound Scanner / Model: UProbe-L (K172750) SONON Ultrasound Imaging System / Model: SONON 300L (K170085) C5 Diagnostic Ultrasound System (K171926)
Dual	Model: H5C10L	Wireless Probe Type Ultrasound Scanner / Model: UProbe-C (K172750) SONON Ultrasound Imaging System / Model: SONON 300C (K151339) C5 Diagnostic Ultrasound System (K171926) Wireless Probe Type Ultrasound Scanner / Model: UProbe-L (K172750) SONON Ultrasound Imaging System / Model: SONON 300L (K170085) C5 Diagnostic Ultrasound System (K171926)

4. Device Description

The SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25) are a wireless ultrasound system that uses pulsed-echo technology to transmit ultrasound images via wireless communication to a Tablet PC or Mobile Phone that utilizes the iOS, Android OS or Windows System.

The SonoMe Wireless Probe Type Ultrasound Scanner and SONOFINDER Wireless Probe Type Ultrasound Scanner are a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system that consists of (i) a commercial off-the-shelf iOS, Android OS or Windows System, (ii) the Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device, (iii) the battery-operated, hand-held Wireless Probe Type Ultrasound Scanner transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System and (iv) User Manual, USB charging cable and Wireless Charger (H5C10L only).

The Wireless Probe Type Ultrasound Scanner software can be downloaded to Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System and utilizes an icon touch-based user interface.

5. Indications for use

SonoMe and SONOFINDER are indicated for examining the adult, pregnant woman, and children. These products are intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are

intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.

6. Technology

The SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25) employ the similar fundamental scientific technology as its predicate device(s).

7. Determination of Substantial Equivalence

The SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25) are substantially equivalent to the predicate devices with regards to intended use, principles of operation, technological characteristics and safety and effectiveness.

As described below, the system has been evaluated for acoustic output, biocompatibility, thermal, electrical, and mechanical safety, and has been found to conform to applicable standards and product specifications that demonstrate that the SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25) are substantially equivalent to the predicate devices.

Comparison Table:

Model: 5C, 5CB, H5C

Comparison Items	**Subject Device**			**Predicate Device**		
Device Name / Model Name	Wireless Probe Type Ultrasound Scanner / Model: 5C (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: 5CB (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: H5C (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: UProbe-C (K172750)	SONON Ultrasound Imaging System / Model: SONON 300C (K151339)	C5 Diagnostic Ultrasound System (K171926)
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.	Bionet Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.	Healcerion Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.
Product Code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYO, ITX	IYO, ITX	IYN, IYO, ITX
Classification	Class 2	Class 2	Class 2	Class 2	Class 2	Class 2
Indication for Use	SonoMe is indicated for examining the adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN),	SonoMe is indicated for examining the adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN),	SonoMe is indicated for examining the adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN),	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GYN) and general (abdominal) imaging.	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GYN) and general (abdominal) imaging.	C5 Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation for Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Comparison Items	Subject Device			Predicate Device		
	abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.			
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Acoustic Output Levels	Track 3	Track 3	Track 3	Track 3	Track 3	Track 3
Display mode	B, B/M, Color, *PDI, **PW	B, B/M	B, B/M, Color, *PDI, **PW	B, B/M	B	B, M, **PW, Color, *PDI, Compound Imaging
Patient Population	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients
Clinical application	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including fetal/obstetrics, gynecology, abdominal	Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals
Principle / Method of Operation	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the	The basic principle is that system transmits ultrasonic energy into patient body and implements post

Comparison Items	Subject Device			Predicate Device		
	body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.
Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	15-inch LCD monitor
Probe Characteristics	Convex, 3.2/5MHz frequency	Convex, 3.2/5MHz frequency	Convex, 3.2/5MHz frequency	Convex, 3.5MHz frequency	Convex, 3.5MHz frequency	Supporting Linear probes (7.5MHz & 6.5MHz) and convex array probes (3.5MHz & 5.0MHz)
Probe Connection to Display	Wireless	Wireless	Wireless	Wireless	Wireless	Non wireless
Off-the-shelf operation system	iOS / Android / Windows	iOS / Android / Windows	iOS / Android / Windows	iOS	iOS / Android	Linux
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Based on an embedded Linux Operating System
System Components	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates	Commercial off-the-shelf iOS or Android mobile device SONON Ultrasound Imaging System software that runs as an app on the mobile device SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates	The C5 Diagnostic Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging system

Comparison Items	Subject Device			Predicate Device		
	wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	wirelessly with iOS mobile device	wirelessly with iOS or Android mobile device	
Patient Contacting Materials	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Evaluated according to FDA recognized standards - ISO 10993-5 and ISO 10993-10	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible and can be disinfected
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

*PDI: Power Doppler Imaging, **PW: Pulse Wave Spectral Doppler

Model: 10L, 14L, SF14L25, 10LB, H10L

Comparison Items	Subject Device					Predicate Device		
Device Name / Model Name	Wireless Probe Type Ultrasound Scanner / Model: 10L (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: 14L (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: SF14L25 (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: 10LB (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: H10L (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: UProbe-L (K172750)	SONON Ultrasound Imaging System / Model: SONON 300L (K170085)	C5 Diagnostic Ultrasound System (K171926)
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.	Bionet Co., Ltd.	Bionet Co., Ltd.	Bionet Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.	Healcerion Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.
Product Code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX
Classification	Class 2	Class 2	Class 2	Class 2	Class 2	Class 2	Class 2	Class 2
Indication for Use	SonoMe is indicated for examining the	SonoMe is indicated for examining the	SONOFINDER is indicated for examining the	SonoMe is indicated for examining the	SonoMe is indicated for examining the	Intended for diagnostic ultrasound echo	Intended for diagnostic ultrasound echo	C5 Diagnostic Ultrasound System is a

Comparison Items	Subject Device					Predicate Device		
	adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral	adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral	adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral	adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral	adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral	imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.	imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thoracic/pleural motion and fluid detection imaging.	general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation for Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Comparison Items	Subject Device					Predicate Device		
	vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.	vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.			
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Acoustic Output Levels	Track 3	Track 3	Track 3	Track 3	Track 3	Track 3	Track 3	Track 3
Display mode	B, B/M, Color, *PDI,** PW	B, B/M, Color, *PDI,** PW	B, B/M, Color, *PDI,** PW	B, B/M	B, B/M, Color, *PDI,** PW	B, B/M	B, Color	B, M, **PW, Color, *PDI, Compound Imaging
Patient Population	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients
Clinical application	General clinical applications, including small organ and peripheral vessel	General clinical applications, including small organ and peripheral vessel	General clinical applications, including small organ and peripheral vessel	General clinical applications, including small organ and peripheral vessel	General clinical applications, including small organ and peripheral vessel	General clinical applications, including small organ and peripheral vessel imaging.	General clinical applications, including fetal/obstetrics, gynecology, abdominal	Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Comparison Items	Subject Device					Predicate Device		
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals
Principle / Method of Operation	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.
Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	15-inch LCD monitor
Probe Characteristics	Linear, 7.5/10MHz frequency	Linear, 10/14MHz frequency	Linear, 10/14MHz frequency	Linear, 7.5/10MHz frequency	Linear, 7.5/10MHz frequency	Linear, 7.5MHz frequency	Linear, 5/7.5/10MHz frequency	Supporting Linear probes (7.5MHz & 6.5MHz) and convex array probes (3.5MHz & 5.0MHz)
Probe Connection to Display	Wireless	Wireless	Wireless	Wireless	Wireless	Wireless	Wireless	Non wireless
Operation System	iOS / Android / Windows	iOS / Android / Windows	iOS / Android / Windows	iOS / Android / Windows	iOS / Android / Windows	iOS	iOS / Android	Linux

Comparison Items	Subject Device					Predicate Device		
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Based on an embedded Linux Operating System
System Components	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	Commercial off-the-shelf iOS mobile device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS mobile device	Commercial off-the-shelf iOS or Android mobile device SONON Ultrasound Imaging System software that runs as an app on the mobile device SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile device	The C5 Diagnostic Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging system
Patient Contacting Materials	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Patient contact materials are biocompatible.	Evaluated according to FDA recognized standards - ISO	All materials with patient contact are biocompatible and can be	All materials with patient contact are biocompatible and can be disinfected

Comparison Items	Subject Device					Predicate Device		
						10993-5 and ISO 10993-10	disinfected	
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

*PDI: Power Doppler Imaging, **PW: Pulse Wave Spectral Doppler

Model: H5C10L

Comparison Items	Subject Device	Predicate Device				
Device Name / Model Name	Wireless Probe Type Ultrasound Scanner / Model: H5C10L (Under Review)	Wireless Probe Type Ultrasound Scanner / Model: UProbe-C (K172750)	SONON Ultrasound Imaging System / Model: SONON 300C (K151339)	Wireless Probe Type Ultrasound Scanner / Model: UProbe-L (K172750)	SONON Ultrasound Imaging System / Model: SONON 300L (K170085)	C5 Diagnostic Ultrasound System (K171926)
Manufacturer	Bionet Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.	Healcerion Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.	Healcerion Co., Ltd.	Guangzhou Sonostar Technologies Co., Ltd.
Product Code	IYN, IYO, ITX	IYO, ITX	IYO, ITX	IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX
Classification	Class 2	Class 2	Class 2	Class 2	Class 2	Class 2
Indication for Use	SonoMe is indicated for examining the adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GYN) and general (abdominal) imaging.	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GYN) and general (abdominal) imaging.	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and	C5 Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation for Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral

Comparison Items	Subject Device	Predicate Device				
	appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.				thoracic/pleural motion and fluid detection imaging.	Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Acoustic Output Levels	Track 3	Track 3	Track 3	Track 3	Track 3	Track 3
Display mode	B, B/M, Color, *PDI, **PW	B, B/M	B	B, B/M	B, Color	B, M, **PW, Color, *PDI, Compound Imaging
Patient Population	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients
Clinical application	General clinical applications, including fetal/obstetrics, gynecology, abdominal, small	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including small organ and peripheral vessel imaging.	General clinical applications, including fetal/obstetrics, gynecology, abdominal	Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral

Comparison Items	Subject Device	Predicate Device				
	organ and peripheral vessel imaging.					Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals
Principle / Method of Operation	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as image of anatomic structures.	The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.
Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	15 inch LCD monitor
Probe Characteristics	Convex: 3.2MHz / 5MHz Linear: 7.5MHz / 10MHz	Convex, 3.5MHz frequency	Convex, 3.5MHz frequency	Linear, 7.5MHz frequency	Linear, 5/7.5/10MHz frequency	Supporting Linear probes (7.5MHz & 6.5MHz) and Convex array probes (3.5MHz & 5.0MHz)
Probe Connection to Display	Wireless	Wireless	Wireless	Wireless	Wireless	Non Wireless
Operation System	iOS / Android / Windows	iOS	iOS / Android	iOS	iOS / Android	Linux
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Based on an embedded Linux Operating System
System Components	Commercial off-the-shelf iOS mobile	Commercial off-the-shelf iOS mobile	Commercial off-the-shelf iOS or Android	Commercial off-the-shelf iOS mobile	Commercial off-the-shelf iOS or Android	The C5 Diagnostic Ultrasound System is

Comparison Items	Subject Device	Predicate Device				
	device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with Tablet PC or Mobile Phone which supports by iOS, Android OS or Windows System.	device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS mobile device	mobile device SONON Ultrasound Imaging System software that runs as an app on the mobile device SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile device	device Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS mobile device	mobile device SONON Ultrasound Imaging System software that runs as an app on the mobile device SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile device	an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging system.
Patient Contacting Materials	Patient contact materials are biocompatible.	Evaluated according to FDA recognized standards - ISO 10993-5 and ISO 10993-10	All materials with patient contact are biocompatible and can be disinfected	Evaluated according to FDA recognized standards - ISO 10993-5 and ISO 10993-10	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible and can be disinfected
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

*PDI: Power Doppler Imaging, **PW: Pulse Wave Spectral Doppler

8. Summary of Non-Clinical Test

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

IEC 60601-1:2005, AMD1:2012 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-37: 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 14971: 2007 Medical devices - Application of risk management to medical devices
IEC 60601-1-6: 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1: 2015 Medical devices - Part 1: Application of usability engineering to medical devices
ISO15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

9. Summary of Clinical Tests

The subject of this premarket submission, SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25), did not require clinical studies to support substantial equivalence.

10. Conclusion

Bionet Co., Ltd. considers the SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SONOFINDER Wireless Probe Type Ultrasound Scanner (Model: SF14L25) to be as safe, as effective, and performance is substantially equivalent to the predicate device.