November 22, 2024

Beijing Konted Medical Technology Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K231354
Trade/Device Name: Pocket Ultrasound System (C10)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX

Dear Ivy Wang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 20, 2023. Specifically, FDA is updating this SE Letter for a typo in the Indications for Use (IFU) statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yanna Kang, OHT8: Office of Radiological Health, 301-796-6704, Yanna.Kang@fda.hhs.gov.

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

Beijing Konted Medical Technology Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

December 20, 2023

Re: K231354
Trade/Device Name: Pocket Ultrasound System (C10)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 10, 2023
Received: November 15, 2023

Dear Ivy Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K231354

Device Name
Pocket Ultrasound System (C10)

Indications for Use *(Describe)*
The Pocket Ultrasound System C10 is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+M), and Pulsed Wave modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications depending on different configuration of array probes:
Convex array probe - Fetal/Obstetrics, Gynecological, Abdominal, Urology
Linear array probe - Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal, Pediatric
Phase array probe - Cardiology, Cardiac Fetal Echo.
The Pocket Ultrasound System C10 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

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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SECTION 2

510(k) Summary

510(k) Summary

I. SUBMITTER

Name: Beijing Konted Medical Technology Co., Ltd.

Address: Room 111,1F, Building 3, No. 27, Yong wang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, Beijing, 102629 PEOPLE'S REPUBLIC OF CHINA

Name of contact person: Deyi Zhu

Tel: +86 10-60219113

Fax: +86 10-60219213

E-Mail: 3245132464@qq.com

Submission date: 2024-01-12

II. Subject Device

Device trade name: Pocket Ultrasound System (Model: C10)

Regulation number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation class: II

Panel: Radiology

Product code: IYN, IYO, ITX

III. Primary Predicative Device & Reference Device

Primary Predicative Device

Submission Number: K162549

Device Trade Name: Lumify Ultrasound System

Applicant: Philips Healthcare

Regulation number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation class: II

Panel: Radiology

Product code: IYN, IYO, ITX

Reference Device

Submission Number: K211746

Device Trade Name: Pocket Ultrasound System

Applicant: GuangDong Youkey Medical Co., Ltd.

Regulation number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation class: II

Panel: Radiology

Product code: IYN, IYO, ITX

IV. Device Description

The Pocket Ultrasound System C10 is designed to be a portable, general-purpose, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through an off-the-shelf (OTS) Android device. the system mainly includes the ultrasound equipment and software application components. The ultrasound equipment is used to complete the ultrasonic imaging function and the software application components are used to complete the image display, measurement, patient information management as well as image storage etc. The Pocket Ultrasound System comprises a series of wireless transducers employing Wi-Fi-based technology to communicate with smartphone devices via direct Wi-Fi. One of the software application components is a software APP (MY USG), which is deployed on Android devices which supported Wi-Fi wireless communication. The other one is the software contained in the ultrasound equipment to control operation of the equipment and transfer images via Wi-Fi to the smartphone devices. This allows the user to export ultrasound images and display them across a range of portable personal devices. The communication protocol between the software APP and the other software contained in the equipment is specially defined for unique connection.

The system is only intended for use by qualified healthcare practitioners (e.g., doctors, nurses, sonographers) who are trained in the use of ultrasound imaging technology. The Pocket Ultrasound System comprises the following:

• A commercial off-the-shelf (COTS) Android smartphone/tablet device.

• the software application (MY USG) running as an App on the COTS device with Android system.

• The ultrasound equipment/Transducers: C10

• Accessory: Wireless Battery Charger & Power Adapter

Different type transducers are available for the Pocket Ultrasound System C10, the frequencies are 2.5 MHz, 3.2 MHz and 7.5MHz respectively depending on different transducer. The Pocket Ultrasound System C10 is designed with four ultrasound modes of operation, including B-mode, Combination Mode (B+M mode), Color Doppler mode and Pulsed Wave Doppler mode.

Real time image and dynamic changes of tissues, organs or vessels will be showed in the image under B-mode, while coloring blood flow can be seen under Color Doppler mode and Pulsed Wave Doppler mode. Combination mode B+M-mode is the combination of the B-mode and M-mode of operation, superimposed on the display. M-mode is defined as time motion display of the ultrasound wave along a chosen ultrasound line, so it's usually applied in diagnosis of cardiovascular diseases.

The system provides real-time images for tissues, organs or blood flow via touch screen of the COTS Android smartphone/tablet device, which, in combination with the embedded software system contained in the ultrasound device, provides users a friendly and convenient graphical interface and makes users be able to easily control the whole system.

V. Indication For Use

The Pocket Ultrasound System C10 is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+M), and Pulsed Wave modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications depending on different configuration of array probes:

Convex array probe - Fetal/Obstetrics, Gynecological, Abdominal, Urology

Linear array probe - Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal, Pediatric

Phase array probe - Cardiology, Cardiac Fetal Echo.

The Pocket Ultrasound System C10 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

VI. Comparison of Technological Characteristics with The Primary Predicate Device

The subjective device and the primary predicate device have the same intended use. The subject device and the primary predicate device have similar technological characteristics as evidenced by the table above. The differences in technological characteristics do not raise new questions regarding safety or effectiveness of the subject device.

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
Product picture				/
Manufacturer	Beijing Konted Medical Technology Co., Ltd.	Philips Healthcare	GuangDong Youkey Medical Co., Ltd.	/
Proprietary name, model	Pocket Ultrasound System C10	Lumify Ultrasound System	Pocket Ultrasound System	/
Regulation name	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system	Same
Regulatory	Class II	Class II	Class II	Same

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
Class				
Product code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	Same
Clinical characteristics				
Indications for Use	The Pocket Ultrasound System C10 is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+M), and Pulsed Wave modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications depending on different configuration of array probes: Fetal/Obstetrics, Gynecological, Cardiac Fetal Echo, Abdominal, Small Parts (breast, thyroid), Cardiology, Carotid, Peripheral Vessel, Muscular-Skeletal, Urology and Pediatric. Convex array probe - Fetal/Obstetrics, Gynecological, Abdominal, Urology Linear array probe - Small Parts (breast, thyroid), Carotid,	Philips Lumify Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B + Color), and M modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac. Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Pocket Ultrasound System (Model: P50, P51, P52, P53, P54, P55, P56) is intended for use by an appropriately trained, qualified physician for ultrasound evaluation. Specific clinical applications and exam types include: Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc), Peripheral Vascular, Urology. This system is suitable for use in hospital and clinical settings.	Same

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
	Peripheral Vessel, Muscular-Skeletal, Pediatric Phase array probe - Cardiology, Cardiac Fetal Echo. The Pocket Ultrasound System C10 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.			
Intended patient population	For use in all patients	For use in all patients	For use in all patients	Same
Intended use environment	Hospital, clinics, home for use by healthcare professionals	Hospital, clinics, home and transport for use by healthcare professionals	Hospitals, clinics	Different, see discussion 1
General technological characteristics				
Working principle	Principle of operation of the Pocket Ultrasound System is based on ultrasonic echo imaging, which is a common medical imaging technology to use the transmission	The system and transducers function in a manner identical to all ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is	The transducers inside the probe are responsible to emitting and receiving ultrasonic waves. When the host pushes pulse with a certain frequency and magnitude onto the	Same

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
	speed of ultrasound in different tissues and reflection degree differences, to get images through computer processing for diagnosis and treatment. The transducers inside the probe are responsible to emitting and receiving ultrasonic waves. When a pulse with a certain frequency and magnitude onto the transducers, then ultrasonic waves are generated through the inverse piezoelectric effect and transmitted to the human body tissue through the probe. When the ultrasonic wave meets the tissue interface, it will generate echoes, which are scattered in different tissues or blood flow and received	transmitted to the transducer. In the transducer, a piezo-electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The differing acoustic properties of the tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this system process the Doppler shift frequencies from the echoes of moving targets (such as blood), to	transducers, a short burst of ultrasound is emitted from transducers and directed into tissue. Echoes are produced as a result of the interaction of sound with tissue, and some of back to the transducers. Echoes come back is then converted into electric signals by transducers and handed to host for further process. The host is mainly responsible for the following: data processing, in response to user instructions. By receiving the echo pulse transmitting time and timing between the transducer and the echo signal can be calculated by the distance between the structure, form the brightness degree of adjacent	

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
	by the probe and converted into electrical signals. The receiver amplifies and processes these electrical signals before transmitting them to the processing unit. Based on the signals received, the processing unit will calculate the intensity and timing of the echoes to form an image.	detect and graphically display the Doppler shifts of these tissues as flow.	image materials. The inherent acoustic impedance difference in the image are different. And through the WIFI transmission and instruction imaging data.	
Design	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Convex and Phase array probes. Cine play back capability Image file archive.	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array and Volume probes. Cine play back capability Image file archive.	Not specified	Same
Operating Controls	Convex: 90~305mm Linear: 20~100mm Cardiac: 90~160mm	Depth Range: 0.003 to >30 cm	Not specified	Different, see discussion 2
	Gain	Gain	Not specified	Same

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
	Focus	Focus	Not specified	Same
	Color box size/position can be adjust	Color box size/position can be adjust	Not specified	Same
	Baseline	N/A	Not specified	Same
	Cine control: drag scroll bar	Cine control: drag scroll bar, press  or 	Not specified	Same
	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Not specified	Same
Operation Mode	B mode B/M mode Color Doppler Mode Pulsed Wave mode	B mode M mode Color Doppler Mode B+C mode	B mode M mode Color Doppler Power Doppler PWD and Combined (B+M; B+CD; B+PD; B+PWD mode)	Different, see discussion 3
Transducers	Convex Array; Phase Array; Linear Array;	Convex Array, Phased Array, Linear Array	Convex Array, Linear Array, Phase Array, Intracavity	Same
Frequency	2.5MHz (phase); 3.2MHz(convex); 7.5MHz(linear)	curvilinear 5-2MHz; linear 12-4MHz	3.5-7.5MHz	Difference, see discussion 4
Probe connection to display unit	Wireless connection via Wi-Fi	Wire connection via USB	Wire connection via USB or Wireless connection via Wi-Fi	Difference, see discussion 5

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
Device and Operating system for the software APP	A commercial off-the-shelf Android device (COTS)	A commercial off-the-shelf Android device (COTS)	A commercial off-the-shelf (COTS) Android mobile device A commercial off-the-shelf (COTS) Windows device	Same
Image display unit	CPU Clock Speed: ≥2GHz; Memory: ≥2G Screen size: ≥4.7 inch; Screen resolution: ≥1334x750 Brightness: capable of ambient light detection and brightness correction. Android version 8.0 or newer	Minimum 50 MB of storage space (plus more for patient data storage) • Color display, minimum 14 cm (5.5 in) • Touch interface • Internally mounted speakers • 1280 x 800 resolution (minimum) • Android 5.0 or later operating system	Windows environment (13.3 inches); Android environment (9.6 inches)	Difference, see discussion 6
Wireless network capability	Communication via Wi-Fi (IEEE 802.11n, 2.4 GHz & 5 G ISM band)	Wireless or cellular networking capability	Wi-Fi	Difference, see discussion 7
Acoustic output levels	Track 3 $I_{spta.3} \leq 720mW/cm^2$ MI ≤ 1.9 TI ≤ 6.0	Track 3 $I_{spta.3} \leq 720mW/cm^2$ MI ≤ 1.9 TI ≤ 6.0	Track 3 $I_{spta.3} = 720mW/cm^2$ MI max.= 1.9 MI display TI display	Same
Power source and power requirement	Rechargeable battery (Li-ion) DC 5V	AC :100V-240V, Frequenzy:50-60Hz	Rechargeable battery (Li-ion) DC 5V	Difference, see discussion 8

Attribute	Subject device	Primary Predicative device (K162549)	Reference device (K211746)	Discussion/ Conclusion
Operating environment	Operating temperature: 0-40 ℃; relative humidity 30-85%; Barometric pressure:700 to 1060 hPa	Operatingtemperature:5-40 ℃; relative humidity 15-95%; Barometric pressure:700 to 1060 hPa	Not specified	Difference, see discussion 9
Ingress Protection degree	Host part of the ultrasound device: IP22 probe part of the ultrasound device: IP27	probe part of the ultrasound device: IP47	Not specified	Difference, see discussion 10
Safety and Effectiveness				
Patient contacting material	Per ISO 10993-5 and ISO 10993-10	Per ISO 10993-5 and ISO 10993-10	Per ISO 10993-5 and ISO 10993-10	Same
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Same
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Same
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Same

Discussion on differences between the subject device and the primary predicate device

Discussion 1: The subject device is not intended to be used in the transport condition, which is applicable in the primary predicate device. As the subject device has restricted use condition than the primary predicate device, such difference will not affect clinical performance and safety of the

subject device.

Discussion 2: The depth range of the subject device is different from the primary predicate device. As the depth size is depending on the type of the probe and the image is able to be enlarged and shrunk by adjusting the depth. Such difference will not affect clinical performance and safety of the subject device.

Discussion 3: The subject device has the B+M mode and PW mode while the primary predicate device has no such two modes, while both B+M mode and PW mode are well-established ultrasound modes commercially available on the market, like the reference device and all modes have been tested according to standard IEC 60601-2-37. Therefore, such difference will not affect clinical performance and safety of the subject device.

Discussion 4: Quality of the image is mainly determined by the array number of transducer elements in principle. There is no difference on image quality when the same body site is detected via transducers with the same array elements under specific frequency range 2-5MHz for convex array or 4-12MHz range for linear array. As frequencies of the subject device are within the frequency range of the primary predicate device, such difference will not affect clinical performance and safety of the subject device.

Discussion 5: Although the subject device is connected via wireless connection while the primary predicate device is connected via USB wire connection, all wireless connection performance and safety have been evaluated accordingly. Therefore, such difference will not affect clinical performance and safety of the subject device.

Discussion 6: Although requirement for image display unit of the subject device is different from the primary predicate device, the min. resolution requirement for both devices is same in actual use, touch screen/speaker function is same, better memory performance and higher operating system is used on the subject device than the primary predicate device. different screen size will not impact image quality as zoom and focus functions

are available. Therefore, such difference will not affect clinical performance and safety of the subject device.

Discussion 7: Although wireless network capability of the subject device is different from the primary predicate device, all wireless connection performance and safety have been evaluated accordingly. Therefore, such difference will not affect clinical performance and safety of the subject device.

Discussion 8: The subject device is supplied by rechargeable battery while the primary predicate device is supplied by power adapter. All safety requirement for the power adapter and battery used have been tested respectively according to applicable standards, such difference will affect clinical performance and safety of the subject device.

Discussion 9: Operating temperature and relative humidity range for the subject device is slightly different from the primary predicate device, while the safety and essential performance of the subject device has been evaluated under specific operational environment. Therefore, such difference will not affect clinical performance and safety of the subject device.

Discussion 10: IP degree for the subject device probe is IP27, which is different from IP47 of the primary predicate device's probe, while both devices are intended to be used for indoor condition, ingress protect against dust with IP2X is enough. As for ingress water protection, both devices are in conformity with IPX7 degree. Therefore, such difference will not affect clinical performance and safety of the subject device.

VII. Summary of Non-clinical Performance

Non-clinical testing for Pocket Ultrasound System C10 was conducted to verify that the subject device met all design specifications, demonstrated safety and essential performance based on current applicable standards, and to demonstrate substantial equivalence to the primary predicate device. The following tests were performed.

- Electric Safety and Electromagnetic Compatibility
  - AAMI/IEC 60601-1:2005 + AMD 1:2012 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 60601-1-11: 2015 Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- Safety test for Rechargeable Li-ion battery
  - IEC 62133-2: 2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
- Usability Evaluation
  - IEC 60601-1-6: 2010 + A1:2013 Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
  - IEC 62366-1: 2014 + A1: 2020 Medical devices – Application of usability engineering to medical devices
- Software validation

Software validation was conducted with a moderate concern according to the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (Document issued on: May 11, 2005).

- Cybersecurity

Cybersecurity is evaluated according to the FDA draft guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (Document issued on October 2, 2014)

- Wireless Coexistence

Wireless Coexistence of the subject device is evaluated according to the following two standards:

- ANSI C63.27: 2017 American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69: 2017 Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems

- Biocompatibility Safety

Biocompatibility Safety is evaluated according to the following standards and guidance:

- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Document issued on: September 4, 2020)
- 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 sensitization

- Non-clinical Performance
  - IEC 60601-2-37: 2007 + A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
  - Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (Document issued on: June 27, 2019)

- Performance Data – Animal

N/A, no animal studies are available for the subject device.

VIII. Summary of Clinical Performance

No clinical studies are available for the subject device. Clinical testing was not required to demonstrate the substantial equivalence of the subject device to its primary predicate device.

IX. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the subject device substantially equivalent to the primary predicate device quoted above. The differences between the subjective device and its primary predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed primary predicate device.