GuangDong Youkey Medical Co., Ltd.
℅ Hu Zeyi
General Manager
Unit 601, 6/F, Block B, Building 1, B1 District,
Hantian Technology City, Dongping Road,
Pingxi Shanghain Village, Guichen Street, Nanhai District
Foshan City, Guangdong 528203
CHINA

February 18, 2022

Re: K211746
Trade/Device Name: Pocket Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 21, 2022
Received: January 21, 2022

Dear Hu Zeyi:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211746

Device Name
Pocket Ultrasound System

Indications for Use *(Describe)*
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), Peripheral Vascular, Urology. The system is suitable for use in hospital and clinical settings.

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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K211746

510(k) Summary

Submitter and Address of Manufacturing Facility	GuangDong Youkey Medical Co., Ltd. Unit 601, 6/F, Block B, Building 1, B1 District, Hantian Technology City, Dongping Road, Pingxi Shanghai Village, Guichen Street, Nanhai District, Foshan City, Guangdong, 528203, CHN Phone: +86-0757-86258600 FAX: 0757-86258600
Date:	2021-5-20
Contact:	Hu Zeyi
Trade name:	Pocket Ultrasound System
Common Name:	Diagnostic Ultrasound System and Transducer
Classification Regulation/ Product Code:	21 CFR 892.1550, Class II/ IYN, IYO, ITX
Establishment Registration Number:	NA
Reason for Premarket Notification:	New Device
Predicate Devices:	K192107 Clarius Ultrasound Scanner

Device Description

The Pocket Ultrasound System is designed to be high-end Pocket Ultrasound Systems and mainly include the ultrasound equipment and APP software components.6 models for the main units are included in this submission, including P50,P51,P52,P53,P53,P55,P56.

The equipment to complete the ultrasonic imaging function; APP complete the image display, measurement, patient information and image storage and other applications. APP can be deployed on Windows or Android devices which supported WIFI. There are two free APPs to support different systems. The communication protocol between APP and the system is specially defined by ourself, and other manufacturers can not use this protocol. The ultrasound device and the APP software transfer images and control instructions via WIFI.

Different type transducers are available for different model of Pocket Ultrasound System, the frequency scope of different transducer are from 3.5MHz to 6.5MHz, refer to the following table .

Model	Is the transducer replaceable	Support transducer	Intended use
P50	Yes	C5-2Fs,C5-2Ks,L11-4Ks, L11-4Gs,C8-5Ks,E10-4Ks	Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid), Peripheral Vascular, Urology
P51	No	C5-2Fs	Gynecology and obstetrics, abdominal kidney
P52	No	C5-2Ks	
P53	No	L11-4Ks	
P54	No	L11-4Gs	Small organ carotid artery
P55	No	C8-5Ks	
P56	No	E10-4Ks	Department of Obstetrics and Gynecology, urinary system

The system provides a variety of modes for flexibly selecting, which include B-mode, M-mode, Color-mode, Power-mode, PW-mode, and combined modes (i.e. B/M- 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-mode, PW-mode or Power-mode. 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 not only provides real-time tissues, organs or blood flow images, but also contains measurement of anatomical structures and analysis packages, which can offer diagnosticians detailed and useful information. The embedded software system along with the touch screen offer users a friendly and convenient graphical interface, which make users be able to easily control the whole system.

Indications for Use

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.

Technological Principle

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 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 image materials. The inherent acoustic impedance difference in the image are different. And through the WIFI transmission and instruction imaging data.

Frequencies vary from about 3MHz for some cardiac, transcranial and deep abdominal applications, to 7MHz for intravascular imaging. Penetration depth and resolution are both associated with the frequency used for imaging, and they are a trade-off as well. The higher frequency is used, better resolution will get, but absorption of the sound energy by tissue also increases which means penetration depth reduces. Proper probes and imaging frequency should be chosen to obtain optimum imaging according to specific application.

Color Doppler imaging takes advantage of the Doppler effect to create a moving image, typically blood flow, of the inside of the body. When the sound bounces off a moving target like a blood vessel, the frequency changes as a result of the Doppler effect. The transducer can detect very subtle frequency changes and record them visually, creating an image which shows where blood is flowing, and in which direction.

Moreover, although the probes need to contact with human body surface in use, the system will not cause any invasive result to or thermal radiation into human body.

Substantial Equivalence Comparison

Equivalent devices are referred to as predicate devices in alignment with the FDA’s standard terminology for comparable devices. The predicate devices elected to demonstrate equivalence is the Clarius Ultrasound Scanner(K192107). A comparison of the subject device and the predicate are provided in the table below:

Criteria for comparison	Subject device	Predicate device (K192107)
Device name	Pocket Ultrasound System	Clarius Ultrasound Scanner
Model	P50,P51,P52,P53,P54,P55, P56	C3, C7, L7, EC7, C3 HD, L7 HD, C7 HD, EC7 HD, L15 HD, PA HD
Intended Use and Classification		
Classification	Class II	Class II
Intended use	The Pocket Ultrasound System is intended for use by a qualified physician for ultrasound evaluation	Diagnostic ultrasound imaging and fluid flow analysis
Indications for Use	Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc),	-Ophthalmic -Fetal -Abdominal

Criteria for comparison	Subject device	Predicate device (K192107)
	Peripheral Vascular, Urology.	–Intraoperative (Ab/Vasc) –Pediatric –Small organ –Adult cephalic –Trans -rectal –Trans -vaginal –Musculo-skel. (Conv.) –Musculo-skel. (Superfic.) –Urology –Gynecology –Cardiac adult –Cardiac pediatric –Peripheral vessel –Carotid –Needle guidance
Technological Characteristics		
Portability	Portable ultrasound system	Portable ultrasound system
Duration of Use	Limited (<24 hours)	Limited (<24 hours)
Transducer Types	Convex Array Linear Array Phased Array Intracavity	–Convex Array –Linear Array –Phased Array –Intracavity
Frequency	3.5-7.5MHz	1-20MHz
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Power Source	Removable battery (Li-ion)	Removable battery (Li-ion)
Wireless Capability	Communicates wirelessly via Wi-Fi	Communicates wirelessly via Wi-Fi and Bluetooth
Acoustic Output Levels	ISPTA max=720 mw/cm^2 MI max =1.9 MI display TI display	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document
Imaging Capacities	B mode M mode Color Doppler Power Doppler PWD and Combined (B+M; B+CD; B+PD; B+PWD)	—B-mode —M-mode —Color Doppler —Power Doppler —PWD — Combined (B+M; B+CD; B+PD; B+PWD)

Criteria for comparison	Subject device	Predicate device (K192107)
Patient Population	For use in all patients	For use in all patients
Users	Healthcare professionals	trained healthcare professionals.
Principle/ Method of Operation	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. The equipment to complete the ultrasonic imaging function; APP complete the image display, measurement, patient information and image storage and other applications. APP can be deployed on Windows or Android devices which supported WIFI. There are two free APPs to support different systems. The communication protocol between APP and the system is specially defined by our-self, and other manufacturers can not use this protocol.The ultrasound device and the APP software transfer images and control instructions via WIFI.	The Clarius Ultrasound Scanner is 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) iOS or Android device. The Clarius Ultrasound Scanner comprises a series of wireless transducers employing Bluetooth and Wi-Fi-based technology to communicate with traditional tablet/smart phone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them across a range of portable personal devices.
Image Display Unit	Windows environment (13.3 inches); Android environment (9.6 inches)	Resolution (in pixels) of 960x640 (or 640x960)
Probe Characteristics	–Convex Array –Linear Array –Phased Array –Intracavity	–Convex Array –Linear Array –Phased Array –Intracavity
Probe	Wireless	Wireless

Criteria for comparison	Subject device	Predicate device (K192107)
Connection to Display		
Off-the-shelf operating system	Windows /Android	iOS/ Android
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device
Safety&Effectiveness		
Patient Contacting Materials	Per ISO 10993-5 and ISO 10993-10	Per ISO 10993-5 and ISO 10993-10
Electrical Safety	Evaluated according to IEC60601-1	Evaluated according to IEC60601-1
EMC	Evaluated according to IEC60601-1-2	Evaluated according to IEC60601-1-2
Performance Safety	Evaluated according to IEC60601-2-37	Evaluated according to IEC60601-2-37

Non-clinical tests

The pocket ultrasound system was subjected to extensive safety, performance, and verification testing. Extensive benchtop tests verified the performance of the device to meet the design requirements in an ideal non-clinical environment. All tests were performed to ensure that the device complies with industry and safety standards.

- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Biocompatibility testing per ISO 10993-5 and ISO 10993-10
- Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment per IEC 60601-2-37
- Acoustic Output Test per FDA Guide for Track 3
- Software verification per FDA Software Guidance

- Clinical accuracy performance per Guidance for Industry and FDA staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
- Wireless performance and coexistence testing

Clinical tests

The subject of this premarket submission, Pocket ultrasound system did not require clinical studies to support substantial equivalence.

Conclusions

The non-clinical testing data support the safety of the device and the performance testing report demonstrate the subject device Pocket Ultrasound System perform as intended and is substantially equivalent to its predicate device with respect to safety and effectiveness.