Beijing Konted Medical Technology Co.,Ltd
% Xuexia Ren
Official Correspondent
(Chengdu Lizhu Technology Co., LTD)
Room 111,1F, Building 3, No. 27 Yong Wang Road,
Daxing Biological Pharmaceutical Base
Daxing District, Beijing, 102629 PEOPLE'S REPUBLIC OF CHINA

August 22, 2024

Re: K241979
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(s): IYN, IYO, ITX
Dated: July 4, 2024
Received: July 5, 2024

Dear Xuexia Ren:

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,

Paramita Sengupta -S

For

Yanna Kang
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241979

Device Name
Pocket Ultrasound System

Indications for Use *(Describe)*
The Pocket Ultrasound System 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K241979

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

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E-Mail: 3245132464@qq.com

Submission date: 2024-07-02

II. Subject Device

Device trade name: Pocket Ultrasound System

Model: C10, C10TX, C10RL, C10RLpro

Regulation number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation class: II

Panel: Radiology

Product code: IYN, IYO, ITX

III. Predicative Device

Submission Number: K231354

Device Trade Name: Pocket Ultrasound System (C10)

Applicant: Beijing Konted Medical Technology 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 (Model: C10, C10TX, C10RL, C10RLpro) 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 / C10TX / C10RL / C10RLpro

  The 4 models have no difference in composition and performance parameters, only the appearance and battery capacity are different.
- Accessory: Wireless Battery Charger & Power Adapter

Different type transducers are available for the Pocket Ultrasound System (Model: C10, C10TX, C10RL, C10RLpro), the frequencies are 2.5 MHz, 3.2 MHz and 7.5MHz respectively depending on different transducer. The Pocket Ultrasound System 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 (Models: C10, C10TX, C10RL, C10RLpro) 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 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

VI. Comparison to predicate device and conclusion

The intended use, main materials, functional design, safety and performance characteristics of the subject device is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Discussion**
Device Name	Pocket Ultrasound System	Pocket Ultrasound System (C10)	--
510(k) Number	K241979	K231354	--
Model	C10, C10TX, C10RL, C10RLpro	C10	--
Manufacture	Beijing Konted Medical Technology Co., Ltd	Beijing Konted Medical Technology Co., Ltd	Same
Classification Name:	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system	SE
Device Classification:	II	II	SE
Clinical characteristics			
Indications for Use	The Pocket Ultrasound System 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:	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:	SE

Elements of Comparison	Subject Device	Predicate Device	Discussion
	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 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	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.	
Intended patient population	For use in all patients	For use in all patients	SE
Intended use environment	Hospital, clinics, home for use by healthcare professionals	Hospital, clinics, home for use by healthcare professionals	SE
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 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	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 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	SE

Elements of Comparison	Subject Device	Predicate Device	Discussion
	probe. When the ultrasonic wave meets the tissue interface, it will generate echoes, which are scattered in different tissues or blood flow and received 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.	probe. When the ultrasonic wave meets the tissue interface, it will generate echoes, which are scattered in different tissues or blood flow and received 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.	
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, Convex and Phase array probes. Cine play back capability Image file archive.	SE
Operating Controls	Convex: 90~305mm Linear: 20~100mm Cardiac: 90~160mm	Convex: 90~305mm Linear: 20~100mm Cardiac: 90~160mm	SE
	Gain	Gain	SE
	Focus	Focus	SE
	Color box size/positive can be adjust	Color box size/positive can be adjust	SE
	Baseline	Baseline	SE
	Cline control: Toggling freeze key	Cline control: Toggling freeze key	SE
Operation Mode	B mode B/M mode Color Doppler mode Pulse Wave mode	B mode B/M mode Color Doppler mode Pulse Wave mode	SE

Elements of Comparison	Subject Device	Predicate Device	Discussion
Transducers	Convex Array; Phase Array; Linear Array	Convex Array; Phase Array; Linear Array	SE
Frequency	Convex Array: 3.2MHz Phase Array: 2.5MHz Linear Array: 7.5MHz	Convex Array: 3.2MHz Phase Array: 2.5MHz Linear Array: 7.5MHz	SE
Probe connection to display unit	Wireless connection via Wi -Fi	Wireless connection via Wi -Fi	SE
Power sourc and power requirement	Rechargeable battery(Li-ion) DC 5V	Rechargeable battery(Li-ion) DC 5V	SE
Device and Operating system for the software APP	A commercial off-the-shelf Android device (COTS)	A commercial off-the-shelf Android device (COTS)	SE
Acoustic output levels	Track 3 $I_{spta.3}$≤720W/cm^2 MI≤1.9 TI≤6.0	Track 3 $I_{spta.3}$≤720W/cm^2 MI≤1.9 TI≤6.0	SE
Safety and Effectiveness			
Patient contacting material	Per ISO 10993-5 and ISO 10993-10	Per ISO 10993-5 and ISO 10993-10	SE
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	SE
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	SE
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	SE

Comparison in Detail(s):

As can be seen from the above comparison table, there is no difference between subject device and predicate device in terms of technical parameters and performance, and they are essentially equivalent.

VII. Summary of Testing

Three new models are added in this submission (C10TX / C10RL / C10RLpro). The new models have no difference in composition and performance parameters from the original model, only the appearance and battery capacity are different.

We have tested two types of batteries with different capacities to ensure that they are both qualified.

Different models of devices have different colors in appearance, and safety tests have been conducted on the pigments that form different colors to ensure that they can come into contact with human skin.

IX. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the subject device are substantially equivalent to the predicate device quoted above. The differences between the subject device and its predicat device do not introduce a new intended use and do no 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. It can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.