July 23, 2026

Beijing Konted Medical Technology Co.,Ltd
% Xuexia Ren
Official Correspondent
Chengdu Lizhu Technology Co., Ltd.
#1179c, 1st Floor, # 2 Niusha Heng St., Jinjiang District
Chengdu, Sichuan Province 610065
CHINA

Re: K261081
Trade/Device Name: Pocket Ultrasound System
(C10MTpro,C10MXpro,C10MSpro,C10MBpro,C10MRpro)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: June 22, 2026
Received: June 23, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.23 14:50:32 -04'00'

For

Yanna Kang, Ph.D.
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)*
K261081

Device Name
Pocket Ultrasound System (C10MTpro,C10MXpro,C10MSpro,C10MBpro,C10MRpro)

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

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.

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510(k) Summary K261081

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: deyiz@konted.cn

Submission date: 2026-06-23

II. Subject Device

Device trade name: Pocket Ultrasound System

Model: C10MTpro,C10MXpro,C10MSpro,C10MBpro,C10MRpro

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/Reference Device

Predicative Device:

Submission Number: K241979

Device Name: Pocket Ultrasound System

Device Model: C10, C10TX, C10RL, C10RLpro

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

Reference Device:

Submission Number: K253448

Device Name: Sonosite MTUltrasound System

Applicant: FUJIFILM SonoSite, Inc.

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 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 professionals who are appropriately trained and qualified in the use of ultrasound imaging technology and the associated clinical applications. 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: C10MTpro/C10MXpro/C10MSpro/C10MBpro/C10MRpro
- Accessory: Wireless Battery Charger & Power Adapter

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.

The following are the parameters of the newly added models:

Items	C10MBpro	C10MRpro	C10MSpro	C10MTpro	C10MXpro
Transducer type	Linear array	Linear array	Linear array	Convex array	Linear array
Nominal frequency	15MHz	19MHz	10MHz	3.5 MHz	7.5 MHz
Frequency class	High frequency	High frequency	High frequency	Low frequency	High frequency
Array length (L) or radius of curvature (R)	L=19.2mm	L=12.8mm	L=25.6mm	R=60mm	L=38.4mm
Scan Depth	20~40mm	0~25mm	0~80mm	⩾160mm	20~100mm
Clinical application	Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal and Pediatric.	Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal and Pediatric.	Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal and Pediatric.	Fetal/Obstetrics, Gynecological, Abdominal, Urology	Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal and Pediatric.

V. Indication 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:

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

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

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/reference devices quoted above.

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

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Discussion
Device Name	Pocket Ultrasound System	Pocket Ultrasound System (C10)	Sonosite MT Ultrasound System	--
510(k) Number	K261081	K241979	K253448	--
Model	C10MTpro,C10MXpro,C10MSpro,C10MBpro,C10MRpro	C10, C10TX, C10RL, C10RLpro	--	--
Manufacture	Beijing Konted Medical Technology Co., Ltd	Beijing Konted Medical Technology Co., Ltd	FUJIFILM SonoSite, Inc.	--
Classification Name:	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system	Ultrasonic Pulsed Doppler Imaging System	SE
Device Classification:	II	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: Convex array probe - Fetal/Obstetrics, Gynecological, Abdominal,	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,	The Sonosite MT Ultrasound System is a general-purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Abdominal Adult Cephalic Cardiac Adult Cardiac Pediatric Fetal-OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial)	Different, see Note 1

	Urology Linear array probe - Small Parts (breast, thyroid), Carotid, Peripheral Vessel, Muscular-Skeletal, Pediatric The Pocket Ultrasound System is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	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.	Ophthalmic Pediatric Peripheral Vessel Small Organ (breast, thyroid, testicles, prostate) Transvaginal Needle Guidance Modes of operation include: B Mode (B), M-Mode (M) (including simultaneous M-mode and anatomical M Mode), PW Doppler (PWD) (including High Pulse Repetition Frequency (HPRF) and simultaneous PWD for certain exam types), Tissue Doppler Imaging (TDI), Continuous Wave Doppler (CWD), Color Power Doppler, Velocity Color Doppler, Color Variance, Tissue Harmonic Imaging (THI), Multi-beam imaging, Steep Needle Profiling, Trapezoid, and combined modes, including duplex and triplex imaging: B+M, B +PWD, B+CWD, B+C, (B+C)+PWD, (B+C)+CWD. This device is indicated for Prescription Use Only. The Sonosite MT Ultrasound System is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients. The system is used with a transducer attached and is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient's	

			body where needed to obtain the desired ultrasound image	
Intended patient population	For use in all patients	For use in all patients	For use in all patients	SE
Intended use environment	Hospital, clinics, for use by healthcare professionals	Hospital, clinics, home for use by healthcare professionals	Hospital, clinics, home for use by healthcare professionals	Different, see Note 5
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 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	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 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	--	SE with the predicated device

	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 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 and Convex 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 with the predicated device
Operating Controls	Convex: ⩾160mm Linear: 0~100mm	Convex: 90~305mm Linear: 20~100mm	--	Different, see Note 2
	Gain	Gain	--	SE with the predicated device
	Focus	Focus	--	SE with the predicated device
	Color box size/positive can be adjust	Color box size/positive can be adjust	--	SE with the predicated device
	Baseline	Baseline	--	SE with the predicated device

	Cline control: Toggling freeze key	Cline control: Toggling freeze key	--	SE with the predicated device
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 with the predicated device
Transducers	Convex Array; Linear Array	Convex Array; Phase Array; Linear Array	Linear Array; Curved Linear Array; Phased Array; Intracavitary	Different, see Note 3
Frequency	C10MTpro: Convex Array 3.5MHz C10MBpro: Linear Array 15MHz C10MRpro: Linear Array 19MHz C10MSpro: Linear Array 10MHz C10MXpro: Linear Array 7.5MHz	Convex Array: 3.2MHz Phase Array: 2.5MHz Linear Array: 7.5MHz	1.0-19.0-18MHz	Different, see Note 4
Probe connection to display unit	Wireless connection via Wi - Fi	Wireless connection via Wi - Fi	--	SE with the predicated device
Power sourc and power requirement	Rechargeable battery(Li-ion) DC 5V	Rechargeable battery(Li-ion) DC 5V	--	SE with the predicated device
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 with the predicated device

Acoustic output levels	Track 3 Ispta.3≤720W/cm2 MI≤1.9 TI≤6.0	Track 3 Ispta.3≤720W/cm2 MI≤1.9 TI≤6.0	Track 3 Ispta.3: 621 mW/cm2 MI:1.72 TI Value: 4.18	SE
Safety and Effectiveness				
Patient contacting material	Per ISO 10993-5 and ISO 10993-10	Per ISO 10993-5 and ISO 10993-10	ISO 10993-1	SE
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	IEC 60601-1	SE
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	IEC 60601-1-2	SE
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	IEC 60601-2-37	SE

Comparison in Detail(s):

Note 1:

The subject device does not have phase array probe. The Convex array probe and Linear array probe have the same indications for use with the predicated device. And the indications are included in the subset of indications cleared on reference device. The subject device does not have Intracavitary.

So the differences of “Indications for use” in the table above will not raise any safety or effectiveness issue.

Note 2:

The Depth of subject device and predicate device looks different. The probe of the subject device have higher frequency, which is to obtain clearer scan images. The higher frequency leads to a change in the scan depth. The safety of the subject device were tested through IEC 60601-2-37 and IEC 62359, the bench testing ensured the accuracy of the frequency and depth measurements.

So the differences of Depth in the table above will not raise any safety or effectiveness issue.

Note 3:

The “Transducers” of subject device and predicate device looks different. Predicate device includes Convex Array; Phase Array; Linear Array. Subject device adds new models to predicate device, the Transducers range is covered by the predicate device. No new types of legendary equipment have been added.

So the differences of “Transducers” in the table above will not raise any safety or effectiveness issue.

Note 4:

C10MTpro has the similar frequency with predicated device on the same transducers. C10MXpro has the same frequency with predicated device on the same transducers. The frequency of C10MBpro, C10MRpro and C10MSpro are higher than that of predicated device, but they are within the range available on the reference device. Performance of the Subject Device will be confirmed through electrical safety, EMC and performance testing.

The Frequency of subject device and predicate device looks different. The probe of the subject device have higher frequency, which is to obtain clearer scan images. The safety of the subject device were tested through IEC 60601-2-37 and IEC 62359, the testing ensured the accuracy of the frequency and depth measurements.

So the differences of Frequency in the table above will not raise any safety or effectiveness issue.

Note 5:

The intended use environment of subject device does not include home environment. The subject device is not designed for home use. The range of environments in which the subject device can be used is included within the use environment of predicted device.

The electrical safety test of the subject device complies with the requirements of IEC 60601-1.

So the differences of intended use environment in the table above will not raise any safety or effectiveness issue.

VII. Summary of Testing

The original models have been successfully evaluated and cleared under K241979. 5 models are added in this submission. The new models features single probe, and the functions can be covered by the original ones. They operate at higher frequency, enabling clearer images to be obtained. The hardware design, materials, and battery used in the new models are all the same as those in the original models.

Therefore, the models submitted this time underwent EMC testing (IEC 60601-1-2:2014) and ultrasonic specific testing (IEC 60601-2-37:2024 and image performance assessment).

IX. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the subject device substantially equivalent to the predicate/reference device quoted above. The differences between the subject device and its predicate/reference device do not introduce a new intended use and do not raise different questions 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.