March 22, 2024

GuangDong Youkey Medical Co., Ltd.
% Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District, Guangzhou
CHINA

Re: K231930
Trade/Device Name: Digital Ultrasonic Diagnostic Imaging System (Model: F6)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 27, 2024
Received: February 27, 2024

Dear Cassie Lee:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

Marjan Nabili -S for

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231930

Device Name
Digital Ultrasonic Diagnostic Imaging System

Indications for Use *(Describe)*
Digital Ultrasonic Diagnostic Imaging System (Model: F6) is a general use ultrasound device intended for use by appropriately qualified and trained healthcare professionals for ultrasound imaging, measurement, display and fluid flow analysis of the human body. Specific clinical applications and exam types include: Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc.), Peripheral Vascular, Urology. Modes of operation include B mode, M mode, Color Doppler, Power Doppler, PWD and Combined (B+M; B+CD; B+PD; B+PWD). This 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.

510(k) Summary for K231930

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: GuangDong Youkey Medical Co., Ltd.

Establishment Registration Number: 3025429169

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Application Correspondent:

Contact Person: Cassie Lee

Company: Share Info (Guangzhou) Medical Consultant Ltd.

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Date of the summary prepared: 3/22/2024

2. Subject Device Information

Type of 510(k): Traditional

Trade Name: Digital Ultrasonic Diagnostic Imaging System

Model: F6

Common Name: Diagnostic Ultrasound System and Transducer

Classification name: Ultrasonic Pulsed Doppler Imaging System

Review Panel: Radiology

Product Code: IYN, IYO, ITX

Regulation Class: II

Regulation Number: 21 CFR 892.1550

3. Predicate Device Information

Primary Predicate Device:

Sponsor: GuangDong Youkey Medical Co., Ltd.

Trade Name: Pocket Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducer

Classification name: Ultrasonic Pulsed Doppler Imaging System

510(K) Number: K211746

Review Panel: Radiology

Product Code: IYN, IYO, ITX

Regulation Class: II

Regulation Number: 21 CFR 892.1550

Reference Device 1:

Sponsor: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

Trade Name: M5 DIAGNOSTIC ULTRASOUND SYSTEM

Common Name: Diagnostic Ultrasound System and Transducer

Classification name: Ultrasonic Pulsed Doppler Imaging System

510(K) Number: K102991

Review Panel: Radiology

Product Code: IYN, IYO, ITX

Regulation Class: II

Regulation Number: 21 CFR 892.1550

Reference Device 2:

Sponsor: Healcerion Co., Ltd.

Trade Name: SONON Ultrasound Imaging System (Model: SONON 300C)

Common Name: Diagnostic Ultrasound System and Transducer

Classification name: Ultrasonic Pulsed Doppler Imaging System

510(K) Number: K151339

Review Panel: Radiology

Product Code: IYO, ITX

Regulation Class: II

Regulation Number: 21 CFR 892.1560

Reference Device 3

Sponsor: Healcerion Co., Ltd

Trade Name: SONON Ultrasound Imaging System (Model: 300L)

Common Name: Diagnostic Ultrasound System and Transducer

Classification name: Ultrasonic Pulsed Doppler Imaging System

510(K) Number: K170085

Review Panel: Radiology

Product Code: IYN, IYO, ITX

Regulation Class: II

Regulation Number: 21 CFR 892.1550

4. Device Description

The Digital Ultrasonic Diagnostic Imaging System is designed to be portable notebook ultrasound systems and mainly include the ultrasound equipment, transducer and adapter.

The equipment to complete the ultrasonic imaging function, host completes the image display, measurement, patient information, image storage, and other applications Standard keyboards, touch panels, and buttons, as well as multifunctional editors, mainly control device operations. The display screen is used to display work interfaces, images, and parameters. Different interfaces are used to connect transducers, other devices, or power supplies.

There are four different types of transducers, namely large convex, linear array, Micro convex, Intracavity, the frequency scope of different transducers is from 2.5MHz to 11MHz.

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.

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.

5. Intended Use / Indications for Use

Digital Ultrasonic Diagnostic Imaging System (Model: F6) is a general use ultrasound device intended for use by appropriately qualified and trained healthcare professionals for ultrasound imaging, measurement, display and fluid flow analysis of the human body. Specific clinical applications and exam types include: Abdominal, Obstetrics, Gynaecology, Small Parts (breast, thyroid, etc.), Peripheral Vascular, Urology. Modes of operation include B mode, M mode, Color Doppler, Power Doppler, PWD and Combined (B+M; B+CD; B+PD; B+PWD). This system is suitable for use in hospital and clinical settings.

6. Test Summary

6.1 Summary of Non-Clinical Tests

Digital Ultrasonic Diagnostic Imaging System has been evaluated the safety and performance by lab bench testing as following:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-37 Edition 2.1 2015

  Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and

essential performance of ultrasonic medical diagnostic and monitoring equipment

- IEC 62133-2 Edition1.0 2017-02

  Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

- ISO 10993-5 Third edition 2009-06-01

  Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10 Fourth edition 2021-11

  Biological evaluation of medical devices - Part 10: Tests for skin sensitization

- ISO 10993-23 First edition 2021-01

  Biological evaluation of medical devices - Part 23: Tests for irritation

- “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Guidance for Industry and Food and Drug Administration Staff”, February 21, 2023: Acoustic Output Test per FDA Guidance for Track 3

- “Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff”, June 14, 2023

- “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Guidance for Industry and Food and Drug Administration Staff”, February 21, 2023: Clinical accuracy performance

6.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

7. Comparison to predicate device

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Digital Ultrasonic Diagnostic Imaging System 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	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Manufacturer	GuangDong Youkey Medical Co., Ltd.	GuangDong Youkey Medical Co., Ltd.	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	Healcerion Co., Ltd.	Healcerion Co., Ltd.	--
Trade Name and model	Digital Ultrasonic Diagnostic Imaging System (model: F6)	Pocket Ultrasound System (model: P50,P51,P52,P53,P54,P55,P56)	M5 DIAGNOSTIC ULTRASOUND SYSTEM	SONON Ultrasound Imaging System (model: 300C)	SONON Ultrasound Imaging System (model: 300L)	--
510(k) Number	K231930	K211746	K102991	K151339	K170085	--
Classification, Indications for Use and Intended Use						
Classification Product Code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYO, ITX	IYN, IYO, ITX	Same
Indications for	Digital Ultrasonic	Pocket Ultrasound	The M5 Diagnostic	The SONON	The SONON	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Use	Diagnostic Imaging System (Model: F6) is a general use ultrasound device intended for use by appropriately qualified and trained healthcare professionals for ultrasound imaging, measurement, display and fluid flow analysis of the human body. Specific clinical applications and exam types include: Abdominal, Obstetrics, Gynaecology, Small Parts (breast,	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	Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for- use in abdomen, gynecology, obstetrics, small parts (breast, testes, thyroid, etc.), pediatrics, transcranial, cardiac, peripheral vascular, urology,	Ultrasound Imaging System (Model: SONON 300C) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	Ultrasound Imaging System (Model: 300L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thoracic/pleural motion and fluid	

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
	thyroid, etc.), Peripheral Vascular, Urology. Modes of operation include B mode, M mode, Color Doppler, Power Doppler, PWD and Combined (B+M; B+CD; B+PD; B+PWD). This system is suitable for use in hospital and clinical settings.	system is suitable for use in hospital and clinical settings.	orthopedics, intracoperative and musculoskeletal (general and superficial) exams.		detection imaging.	
Technological Characteristics						
Portability	Portable ultrasound system	Portable ultrasound system	Portable ultrasound system	Portable ultrasound system	Portable ultrasound system	Same
Duration of Use	Limited (<24 hours)	Limited (<24 hours)	Limited (<24 hours)	Limited (<24 hours)	Limited (<24 hours)	Same
Transducer	Convex Array	Convex Array	linear array, convex	Convex	Linear	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Types	Linear Array Intracavity	Linear Array Phased Array Intracavity	array and phased array			
Frequency	2.5-11.0 MHz	3.5-7.5MHz	2.0-12.0 MHz	Convex, 3.5 MHz frequency	Linear, 5MHz / 7.5MHz / 10MHz frequency	Similar Note 1
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Same
Power Source	Power adapter: Input AC 100~240V/60Hz 0.9A; Output DC 15V 2.4A Internal power supply: DC 11.1V 8400mAh (Li-ion)	Removable battery (Li-ion)	110V-120V	Battery (Li-ion)	Battery (Li-ion)	Different Note 2
Wireless Capability	Not applicable	Communicates wirelessly via Wi-Fi	Not applicable	Wireless	Wireless	Same
Acoustic Output	SPTA max=720 mw/cm^2	ISPTA max=720	SPTA max=720	ISPTA.3 = 0.0627	Below Track 3 FDA	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Levels	MI max =1.9 MI display TI display	mw/cm^2 MI max =1.9 MI display TI display	mw/cm^2 MI max =1.9 MI display TI display	W/cm2 MI = 0.7861 TIS = 0.2535 Ipa.3@MI.max = 11.6369 W/cm2	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 and Combined (B+M; B+CD; B+PD; B+PWD)	B mode M mode Color Doppler Power Doppler PWD and Combined (B+M; B+CD; B+PD; B+PWD, B+CD+PWD, PD+PW+B)	Pulsed-echo ultrasound Mode B (2D) scan	Pulsed-echo and Doppler ultrasound Mode B (2D), Color scan	Same
Patient	For use in all patients	For use in all patients	For use in all patients	For use in all patients	For use in all patients	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Population						
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Same
Image Display Unit	Display screen	Windows environment (13.3 inches) Android environment (9.6 inches)	Display screen	Mobile device (4 to 10 inches approximately)	Mobile device (4 to 10 inches approximately)	Same
Probe Connection to Display	Wired	Wireless	Wired	Wireless	Wireless	Same
Off-the-shelf operating system	Android	Windows /Android	Not published	iOS / Android	iOS / Android	Same
Software	Embedded software	Run as an app on off-the shelf mobile device	Embedded software	Runs as an app on off-the-shelf mobile	Runs as an app on off-the-shelf mobile	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
				device	device	
Material						
Patient contact materials	All types Transducer: Shell: PC+ABS; Acoustic lens: Silicone	All types Transducer: Shell: PC+ABS; Acoustic lens: Silicone	Not published	All patient-contact materials are biocompatible and can be disinfected	All patient-contact materials are biocompatible and can be disinfected	Same
Contact area	Intact skin and mucous membranes	Intact skin and mucous membranes	Intact skin and mucous membranes	Not published	Not published	Same

Comparison in Detail(s):

Note 1:

Although the “Frequency” of the subject device is different from the predicate device, the frequency range of the subject device is within the range of the predicate device K102991 So, the slight difference will not affect the safety and effectiveness of the subject device.

Note 2:

Although the “Power Source” of the subject device is different from the predicate device, it meets the requirements of safety and performance standards IEC 60601-1and IEC 62133-2. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

8. Final Conclusion:

The subject device Digital Ultrasonic Diagnostic Imaging System has all features of the primary predicate device (K211746). The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the primary predicate device (K211746).