October 24, 2024

Telefield Medical Imaging (Shenzhen) Limited
Dolly Xiong
Regulatory Affairs Manager
Room A614-A619, A701-A703, National Key Lab Platform Building
No.1 Yuexing Second Road, Hi-tech Industrial Park, Nanshan Dist
Shenzhen, Guangdong 518054
CHINA

Re: K241554
Trade/Device Name: Portable Digital Color Doppler Ultrasound System (SCN201D, SCN201L)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 10, 2024
Received: May 31, 2024

Dear Dolly Xiong:

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.

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,

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

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)*
K241554

Device Name
Portable Digital Color Doppler Ultrasound System (SCN201D, SCN201L)

Indications for Use *(Describe)*
The Portable Digital Color Doppler Ultrasound System is intended for ultrasound imaging in B (2D), Color Doppler and Pulsed Wave imaging modes.

It is indicated for ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Small Organ, Musculoskeletal, Peripheral Vessel, Urology, and Carotid.

The Portable Digital Color Doppler Ultrasound System is intended for use in environments where healthcare is provided by appropriately trained and qualified 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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K241554
Date:	May 10th, 2024
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Submitter:	Telefield Medical Imaging (Shenzhen) Limited Room A614-A619, A701-A703, National Key Lab Platform Building, No.1 Yuexing Second Road, Hi-tech Industrial Park, Nanshan District, Shenzhen, Guangdong, People's Republic of China Tel: 86-755-83566313 Fax: 86-755-83571649 E-mail: info@scolioscan.com
Contactor:	Dolly Xiong Regulatory Affairs Manager E-mail: dolly.xiong@scolioscan.com Tel: 86-755-83566313 Fax: 86-755-83571649

2. Device Description

Device Name:	Portable Digital Color Doppler Ultrasound System
Model Name:	SCN201D, SCN201L
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Device Class:	2
Regulation Number:	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570
Review Panel:	Radiology
Indications for use:	The Portable Digital Color Doppler Ultrasound System is intended for ultrasound imaging in B (2D), Color Doppler and Pulsed Wave imaging modes. It is indicated for ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Small Organ, Musculoskeletal, Peripheral Vessel, Urology, and Carotid. The Portable Digital Color Doppler Ultrasound System is intended for use in environments where healthcare is provided by appropriately trained and qualified healthcare professionals.
Device Description:	The Portable Digital Color Doppler Ultrasound System is a portable, general-purpose, software-controlled ultrasound system. It consists of a handheld ultrasound main unit and software. The system is engineered to produce real-time ultrasound images, with an emphasis on capturing detailed anatomical structures and evaluating blood flow patterns using

color Doppler technology. It includes features for measurements, image storage and review, as well as printing and recording capabilities. This portable system enables point-of-care ultrasound applications, providing healthcare professionals with a convenient way to visualize anatomical structures and assess blood flow dynamics.

3. Predicate Devices Identification

	Primary Predicate Device	**Reference Device 1**	**Reference Device 2**
510(k) Number	K150204	K182845	K201967
Marketing Clearance Date	04/10/2015	12/27/2018	02/26/2021
Product Name	DC-70/DC-70T/DC-70 PRO/DC-70 EXP Diagnostic Ultrasound Systems	minisono	Digital Color Doppler Palm Ultrasound System (SonoEye P2)
Manufacturer	Shenzhen Mindray Bio-medical Electronics Co., LTD	ALPINION MEDICAL SYSTEMS Co., Ltd.	CHISON Medical Technologies Co., Ltd.

4. Substantially Equivalent Comparison

Parameters	Proposed Device	Primary Predicate Device	Reference device 1	Reference device 2	Remark
510(k) Number	K241554	K150204	K182845	K201967	--
Marketing clearance date	No	April 10, 2015	December 27, 2018	February 26, 2021	--
Device Name	Portable Digital Color Doppler Ultrasound System	DC-70/DC-70T/DC-70 PRO/DC-70 EXP Diagnostic Ultrasound Systems	minisono	Digital Color Doppler Palm Ultrasound System	--
Model Name	SCN201D, SCN201L	DC-70/DC-70T/DC-70 PRO/DC-70 EXP	minisono L3-12, minisono C1-6	SonoEye P2	--
510(k) Owner	Telefield Medical Imaging (Shenzhen) Limited	Shenzhen Mindray Bio-medical Electronics Co., LTD	ALPINION MEDICAL SYSTEMS Co., Ltd.	CHISON Medical Technologies Co., Ltd.	--
Regulation Number	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570, 21 CFR 892.2050	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570	21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570	Same
Product Code	IYN, IYO, ITX	IYN, IYO, ITX, LLZ	IYN, IYO, ITX	IYN, IYO, ITX	Same
Device Class	2	2	2	2	Same
Review Panel	Radiology	Radiology	Radiology	Radiology	Same
Intended use	The Portable Digital Color Doppler Ultrasound System is intended for ultrasound imaging in B (2D), Color Doppler and Pulsed Wave imaging modes. It is indicated for ultrasound	DC-70/DC-70T /DC-70 PRO/DC-70 EXP Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal,	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal; Pediatric, Small Organ (breast, testes, thyroid);	The Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, Color Doppler, Combined(B+Color), Pulsed Wave and Fusion Harmonic Imaging	Similar

	imaging and fluid flow analysis in the following applications: Abdominal, Small Organ, Musculoskeletal, Peripheral Vessel, Urology, and Carotid. The Portable Digital Color Doppler Ultrasound System is intended for use in environments where healthcare is provided by appropriately trained and qualified healthcare professionals.	abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.	Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Peripheral Vascular (PV); and Urology (including prostate).	modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Pediatrics, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid. The Digital Color Doppler Palm Ultrasound System is intended for use in environments where healthcare is provided by healthcare professionals.	
Type of use	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Same
Operation Mode	B (2D) mode Color Doppler mode Pulsed Wave mode	B-Mode, M-Mode, PW-Mode, CW-Mode, Color-Mode, Power/Dirpower Mode, THI or the combined mode (B/M-Mode, B/PW-mode, B/PW/Color)	B mode M mode PWD mode Color Doppler Power Doppler Tissue Harmonic Imaging Combined (B/Color Doppler, B/PWD, B/Color Doppler/PWD)	B (2D) mode B/M mode Color Doppler mode Combined (B+Color)mode Pulsed Wave mode Fusion Harmonic Imaging modes	Similar
Application area	Abdominal Small Organ Musculoskeletal Peripheral Vessel Carotid	Fetal, abdominal, pediatric, small organ, neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric	Fetal Abdominal Pediatric Small Organ Musculo-skeletal	Pediatrics Small Organ Musculoskeletal Peripheral Vessel Carotid	Similar

	Urology	cardiac, peripheral vessel and urology	Peripheral Vascular (PV) Urology		
Transducer Types	Linear array Convex Array	Linear array Convex Array	Linear array Convex Array	Linear array	Same
Intended user	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals	Same
Applied environment	Environments where healthcare is provided by healthcare professionals	Environments where healthcare is provided by healthcare professionals	Environments where healthcare is provided by healthcare professionals	Environments where healthcare is provided by healthcare professionals	Same
Acoustic Output Track	Track 3	Track 3	Track 3	Track 3	Same
Measurements	B (2D) mode: Distance, Trace, Depth, Angle, Circumference, Area Doppler mode: Velocity	2D mode: Distance, Area, Angle, Volume, Trace Area, Circumference, Heart Rate, Volume Doppler mode: Velocity, Time	2D mode: Distance, Ellipse, Trace, %Stenosis, Volume M mode: Distance, Time, %Stenosis Doppler mode: Velocity, Time	2D mode: Depth, Distance, Area, Volume Doppler mode: D Velocity, Time B/M mode: Distance, Time, HR	Similar
Design	Handheld	Floor Standing	Handheld	Handheld	Similar
Power supply	DC 5V	100-127V ～ or 220-240 V ～ 50/60Hz	DC 5V	DC 5V	Similar
Operating environment	Ambient temperature: 5℃ ~ 40℃ Relative humidity: 30% ~ 85% (No condensation) Atmospheric pressure: 80kPa ~ 106kPa	Temperature: 0°C~40°C Relative humidity: 30%~85% (no condensation) Atmospheric pressure: 700hPa~1060hPa	Temperature: 10-35℃; Relative humidity: 30-75%; Barometric pressure: 700 to 1060 hPa	Temperature: 10-38℃; Relative humidity: 30-75%; Barometric pressure: 700 to 1060 hPa	Similar
Transportation &	Ambient temperature: -20℃ ~	Temperature: -20°C~55°C	Temperature: -25-60℃;	Temperature: -10-50℃;	

Storage environment	55℃ Relative humidity: 15% ~ 95% (No condensation) Atmospheric pressure: 80kPa ~ 106kPa	Relative humidity: 20%~95% (no condensation) Atmospheric pressure: 700hPa~1060hPa	Relative humidity: 20-90% Barometric pressure: 700 to 1060 hPa	Relative humidity: ≤80%, non-condensing; Barometric pressure: 700 to 1060 hPa	
Weight	SCN201D: 500g SCN201L: 450g	<85kg	minisono L3-12: 175g minisono C1-6: 180g	200g	Similar
Dimensions	SCN201D: 182mm×97mm×177mm SCN201L: 167mm×71mm×176mm	855±5mm(Length)×510±5mm (Width) × 1190±5mm (Height)	minisono L3-12: 150mm×62.5mm×25.5mm minisono C1-6: 157mm×62.5mm×25.5mm	64mm×170mm×24mm	
Materials	ABS, Silicone	Unpublished	Unpublished	Unpublished	Similar
Compliant standards	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC /TR 60601-4-2 IEC 60601-1-6 IEC 62366-1 IEC 60601-2-37 IEC 62359 NEMA UD 3	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 62366 IEC 60601-2-37 NEMA UD 2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-2-37 ISO 10993-1 AIUM/NEMA UD 2	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1	Similar
Positioning system	Optical positioning system	Magnetic navigator positioning system	Unpublished	Unpublished	Similar
Labeling	Meet the FDA requirements	Meet the FDA requirements	Meet the FDA requirements	Meet the FDA requirements	Same

The proposed devices have the similar indication for use as the predicate devices as well as comparable technical and performance properties and characteristics, and the minor differences don't raise any additional questions for safety and effectiveness. Therefore, the proposed devices are substantially equivalent to the predicate devices.

5. Non-clinical Testing Summary

The Portable Digital Color Doppler Ultrasound System has passed testings according to:

1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];

2) 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;

3) IEC /TR 60601-4-2 Edition 1.0 2016-05, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems;

4) IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;

5) IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices;

6) 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;

7) IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields;

8) NEMA UD 3-2004 (R2009), Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment;

9) IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes.

6. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission, the Portable Digital Color Doppler Ultrasound System, is as safe, as effective, and performs as well as the legally marketed predicate devices.