Shenzhen Wisonic Medical Technology Co., Ltd.
℅ Jiang Xiaosan
Management Representative
1st, 2nd, 5th & 6th Floor, NO.6 Building,
Pingshan Technology Park, Taoyuan Street, Nanshan District
Shenzhen, Guangdong 518055
CHINA

December 2, 2021

Re: K211886
Trade/Device Name: Clivia series Diagnostic 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: October 25, 2021
Received: November 1, 2021

Dear Jiang Xiaosan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211886

Device Name
Clivia series Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Clivia series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It intended for use in Fetal/Obstetrics, Abdominal/GYN, Pediatrics, Small Organ(breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric), peripheral vessel and Urology exams.

The operator for Clivia series Diagnostic Ultrasound System is intended for professional clinical staff or the qualified and trained personnel with experience in the use of ultrasound diagnostic equipment. The device is intended to be used in hospital or clinics.

Modes of operation include: B-Mode, M-Mode, Color Mode, Power (Dirpower)-Mode, PW Doppler Mode, CW Doppler Mode, 3D/4D, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging(TDI), Anatomic M(AMM) and combined mode.

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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K211886

510(k) Summary

1. Submitter

Manufacturer: Shenzhen Wisonic Medical Technology Co., Ltd.

Address: 1st, 2nd, 5th & 6th Floor, NO.6 Building, Pingshan Technology Park, Taoyuan Street, Nanshan District, Shenzhen. Guangdong, 518055, P.R. CHINA

Contact person: Name: Jiang Xiaosan

Phone: +86-755-86007788

Fax: +86-755-86007799

Date prepared: June 08, 2021

2. Device

Name of Device: Clivia series Diagnostic Ultrasound System

Models: Clivia 90Elite, Clivia 90Exp, Clivia 90Nova, Clivia 90, Clivia 90T, Clivia 90Pro, Clivia 90Plus, Clivia 90Go

Common/Usual Name: Diagnostic Ultrasound System

Regulatory Class II

Product Code: IYN, IYO, ITX

3. Device Description

The proposed Clivia series Diagnostic Ultrasound System is a general-purpose, Track 3, diagnostic ultrasound device, intended for ultrasound imaging, measurement and analysis of the human body and fluid that provides digital acquisition, processing and display capabilities.

The Clivia series Diagnostic Ultrasound System can be controlled both by touch screen or the control panel. Its basic function is to acquire and display ultrasound data in B-Mode, M-Mode, Color-Mode, Power(Dirpower)-Mode, PW-Mode, CW-mode, 3D/4D, Holo PW, Anatomic M(AMM), Tissue Doppler Imaging(TDI) and the combined modes. The system can also measure anatomical structures and offer software analysis packages performance to provide information based on which the competent health care professionals can make the diagnosis.

Ten different models of probes are available for the Clivia series, that is C6-1B-H, C6-2-H, C9-3-H, L15-4NB-H, L22-10-H, LH15-6-H, SP5-1-H, P8-3-H, EV11-3-H, D7-2-H.

The Clivia series Diagnostic Ultrasound System has the capability for displaying the patient's ECG and trace synchronized to the scanned image. This allows the user to view an image from a specific time of the ECG signal. ECG is not intended for monitoring or diagnosis.

The Clivia series Diagnostic Ultrasound System has four batteries in total that allows for scanning or other operation without the need to plug in to an electrical outlet. The system is capable of wireless communication and a barcode reader is available to be used as an input device. System meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices.

4. Indications for Use

The Clivia series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It intended for use in Fetal/Obstetrics, Abdominal/GYN, Pediatrics, Small Organ(breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric), peripheral vessel and Urology exams.

The operator for Clivia series Diagnostic Ultrasound System is intended for professional clinical staff or the qualified and trained personnel with experience in the use of ultrasound diagnostic equipment. The device is intended to be used in hospital or clinics.

Modes of operation include: B-Mode, M-Mode, Color Mode, Power (Dirpower)-Mode, PW Doppler Mode, CW Doppler Mode, 3D/4D, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging(TDI), Anatomic M(AMM) and combined modes.

5. Comparison of Technological Characteristics between Proposed Subject Device and Predicate Device

Predicate Device	Manufacturer	Device Name	510(k) Number
Predicate device	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC	Venue	K180599
Reference device	Shenzhen Mindray Bio-medical Electronics Co., LTD.	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85 Diagnostic Ultrasound System	K173471
Reference device	Shenzhen Wisonic Medical Technology Co., Ltd.	Navi e/Navi s/Navi X Diagnostic Ultrasound System	K180461

Clivia series Diagnostic Ultrasound System is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness:

- The Proposed device and predicate device Venue (K180599) have similar intended use, the intend use of the Proposed device are covered in the intended use of the predicate device.
- The proposed device has similar operation modes to the predicate device Venue (K180599), except for Holo PW. The Holo PW has been cleared in reference device (K180461);
- The proposed device has the same function with the predicate device Venue (K180599), except for wiGuide. For wiGuide, it has identical operating principals and specifications as the NGS function of the reference device (K180461), the difference between wiGuide and NGS is only the name.

- The proposed device has similar ports to the predicate device Venue (K180599)
- The proposed device has similar peripheral devices to the predicate device Venue (K180599), except for Magnetized Cup and Foot switch. For Magnetized Cup, it has been cleared in reference device (K180461). For Foot switch, it can be considered same as reference device (K173471).
- The acoustic power levels of the proposed device are below the limits of FDA, which is the same as the predicate device (K180599).
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The proposed device and predicate device Venue (K180599) have been designed in compliance with approved electrical and physical safety standards.

The difference in technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

6. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

6.1 Biocompatibility testing

The biocompatibility evaluation for the Clivia series Diagnostic Ultrasound System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,' and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Clivia series Diagnostic Ultrasound System. The system complies with the IEC 60601-1 and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

6.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "Moderate" level of concern.

6.4 Acoustic testing

Acoustic testing is conducted on the Clivia series Diagnostic Ultrasound System in accordance with the NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.

6.5 Clinical study

The subject of this premarket submission, Clivia series Diagnostic Ultrasound System, did not require clinical studies to support substantial equivalence.

7. Conclusion

The differences between the Clivia series Diagnostic Ultrasound System and its predicate device do not raise different questions of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Clivia series Diagnostic Ultrasound System should perform as intended in the specified use conditions.

From the results of performance data described, Wisonic concludes that the Clivia series Diagnostic Ultrasound System is substantially equivalent to the predicate device in terms of safety and effectiveness.