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

July 30, 2021

Re: K210154
Trade/Device Name: Labat 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: June 8, 2021
Received: June 21, 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)*
K210154

Device Name
Labat series Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Labat series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small organ (breast, thyroid, testes,etc.), neonatal cephalic, adult cephalic, trans-vaginal, trans-rectal, musculo-skeletal (conventional and superficial), cardiac (adult and pediatric), trans-esoph.(cardiac), peripheral vessel and urology exams.

The operator for Labat 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, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging, Anatomic M 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.

510(k) Summary K210154

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: November 12, 2020

2. Device

Name of Device:	Labat series Diagnostic Ultrasound System
Models:	Labat SE, Labat SP, Labat SG, Labat PE, Labat PG, Labat TE, Labat TG, Labat IE and Labat IG.
Common/Usual Name:	Diagnostic Ultrasound System
Regulatory Class	II
Product Code:	IYN, IYO, ITX

3. Device Description

The proposed Labat 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 Labat series Diagnostic Ultrasound System is a touch screen controlled ultrasonic system. Nine models for the main units are included in this submission, that is Labat SE, Labat SP, Labat SG, Labat PE, Labat PG, Labat TE, Labat TG, Labat IE and Labat IG. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, Color-Mode, Power (Dirpower)-Mode, PW-Mode, CW-mode, 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.

The Labat series Diagnostic Ultrasound System consists of the main unit, ultrasound probes, ECG cables, gel warmer, magnetic cup, foot switch, barcode reader, laser

marker, TEE(transesophageal echocardiography) architecture arm, etc.

Ten different models of probes are available for the Labat series, that is C6-1B-H, C8-3-H, L15-4WB-H, L15-4NB-H, L22-10-H, L15-6-H, LH15-6-H, SP5-1-H, EV11-3-H, P7-3T-H.

4. Indications for Use

The Labat series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small organ (breast, thyroid, testes,etc.), neonatal cephalic, adult cephalic, trans-vaginal, trans-rectal, musculo-skeletal (conventional and superficial), cardiac (adult and pediatric), trans-esoph.(cardiac), peripheral vessel and urology exams.

The operator for Labat 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, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging, Anatomic M and combined mode.

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

510(k) Clearance	Trade Name	Manufacturer	Predicate Device
K180912	TE7/TE5 Diagnostic Ultrasound System	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd	Predicate Device
K163712	Clover 50/Clover 60/Clover 70 Diagnostic Ultrasound System	Shenzhen Wisonic Medical Technology Co., Ltd.	Reference device
K180461	Navi e/ Navi s/ Navi X Diagnostic Ultrasound System	Shenzhen Wisonic Medical Technology Co., Ltd.	Reference device
K201693	DC-90/ DC-90S/ DC-90Q/ DC-95/ DC-95S/ DC-88/	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd	Reference device

	DC-88S/ DC-80A/ DC-80AExp/ DC-80A Pro/ DC-8X/ DC-8Q/ DC-81/ DC-82 Diagnostic Ultrasound System		

Labat series Diagnostic Ultrasound System has the same technology as the predicate device(K180912). The proposed device has the same intended uses and similar operation modes as the predicate device. All systems have the same capability in term of measurements and calculation functions .

The proposed device has the same intended uses and probe type as predicate device TE7/TE5(K180912);

The acoustic power levels of the proposed device are below the limits of FDA, which is the same as the predicate device (K180912);

The proposed device has similar operation modes as the predicate device TE7/TE5(K180912), except for Holo PW, AMM and TDI. For Holo PW and TDI, it has been cleared in reference device (K163712). For AMM mode, it can be considered same as reference device (K201693);

The proposed device has the same function, except for Needle Guide System(wiGuide), which detects the position and orientation of magnetized needles in the presence of the probe and displays this information relative to the ultrasound image. This function has similar operating principals and specifications as the reference device (K180461);

This 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.

Biocompatibility testing

The biocompatibility evaluation for the Labat 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 or intracutaneous reactivity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Labat series Diagnostic Ultrasound System. The system complies with the IEC 60601-1, IEC 60601-2-18 and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

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.

Acoustic testing

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

Clinical study

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

7. Conclusion

The differences between the Labat 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 Labat series Diagnostic Ultrasound System should perform as intended in the specified use conditions.

From the results of performance data described, Shenzhen Wisonic concludes that the Labat series Diagnostic Ultrasound System is as safe and as effective as the predicate devices.