September 15, 2023

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

Re: K230066
Trade/Device Name: Carnation series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, ITX and IYO
Dated: August 11, 2023
Received: August 17, 2023

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,

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

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)*
K230066

Device Name
Carnation series Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Carnation 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 and superficial), cardiac (adult and pediatric), peripheral vessel, urology, Thoracic/Pleural, Vascular Access exams.

The Carnation series Diagnostic Ultrasound System is a general purpose diagnostic ultrasound system for use by qualified healthcare professionals. The clinical environments where the Carnation series can be used include critical care and emergency room environments, as well as point-of care areas in offices, clinical and hospital settings for diagnosis of patients.

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(TDI), Anatomic M-mode(AMM), Color M Mode(CM), Panoramic Imaging(PANO), 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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510(k) Summary K230066

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Submitter

Submitter:	Shenzhen Wisonic Medical Technology Co., Ltd..
Address:	1st, 2nd, 5th and 6th Floor, NO.6 Building, Pingshan Technology Park, Taoyuan Street, Nanshan District, 518055 Shenzhen, P.R.China
Contact Person:	Jiang Xiaosan
Tel:	(+86) 755 86007788
Fax:	(+86) 755 86007799
Date prepared	January 3, 2023

2. Device

Device Name:	Carnation series Diagnostic Ultrasound System
Common/Usual Name:	Diagnostic Ultrasound System
Models:	Carnation, Carnation Fast, Carnation T, Carnation Exp Carnation Neo, Carnation+, Carnation Pro, Carnation Ultra
Regulation number:	21 CFR 892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic
Regulation Class:	II
Product Code:	IYN, ITX, IYO

3. Identification of Predicate Device

Predicate Device	Manufacturer	Device Name	510(k) Control 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.	Clivia series Diagnostic Ultrasound System	K211886

4. Device Description

Medical ultrasound imaging technology aims at exploring and acquiring human physiological or diagnosing information by using ultrasound wave as the information carrier. As one of four major imaging technologies, medical ultrasound technology is proved to be safe, convenient, inexpensive, and can be extensively applied in clinical diagnosis, recovery, and clinical screen guidance.

The proposed Carnation 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 Carnation series Diagnostic Ultrasound System is a touch screen controlled ultrasonic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, Color-Mode, Power(Dirpower)-Mode, PW Doppler Mode, CW Doppler mode, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging(TDI), Anatomic M-mode(AMM), Color M Mode(CM), Panoramic Imaging(PANO), and combined mode. 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.

Holo PW is based on the echo planar imaging, and forms the planar data by emitting and receiving multiple beams to synchronously display the blood flow at multiple sampling gates. From the perspective of application, HOLO PW is different from conventional pulsed Doppler imaging (PW) mainly in the following two points:

1） Conventional PW has only one sampling gate, and there is a corresponding spectrum diagram corresponding to the blood flow information of the sampling gate; HOLO PW is set as three sampling gates, and there are three spectral graphs corresponding to the blood flow information of sampling gates.

2） During film playback after freezing, the sampling gate position of conventional PW is not adjustable; When imaging HOLO PW, there is a region of interest (ROI). After freezing, all three sampling gates can change

within the ROI range, and the spectrum is refreshed with the change of sampling gate

The Carnation series Diagnostic Ultrasound System consists of the main unit, ultrasound probes, ECG lead wire, Magnetic cup, Foot switch, Scanner, USB headset, Camera and Black/white video printer.

The Carnation series Diagnostic Ultrasound System utilizes a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes. Some biopsy kits are available for needle-guidance procedures. The system also includes several automated measurement function: wiCalc_Diaph, wiCalc_Vas, wiCalc_Vol.Flow, Automatic trace, wiCalc_VTI, wiCalc_IVC, wiCalc_IMT, those measurement function can assist users to carry out relevant measurement automatically. The output results of those automatic measurement function are for reference only by users, and the final results need to be confirmed and modified by users based on professional knowledge.

1） wiCalc_Diaph is used to automatically calculate the diaphragm movement amplitude (Diaph.Disp), diaphragm acceleration (Diaph.Accel), inspiratory time (Insp.Time), diaphragm speed (Diaph.Vel); and to evaluation the function of the diaphragm.
2） wiCalc_Vas is used to automatically calculate the blood vessel depth, blood vessel diameter, and blood vessel area of the short axis of the blood vessel.
3） wiCalc_Vol.Flow is used to automatically calculate the volume of blood flow.
4） wiCalc_VTI (Velocity-Time Integral) is mainly used to calculate the Velocity-Time Integral automatically, so as to evaluate the cardiac function.
5） wiCalc_IVC is used to automatically calculate the IVC inner diameter. It can be used to assessment the cardiac function and peripheral volume.
6） wiCalc_IMT is used to automatically recognize the carotid and calculate the vertical distance between the upper edge of the intima and the upper edge of the adventitia of the posterior wall of the blood vessel.
7） Automatic trace is used to traces the PW waveform automatcilly, and automatically measure heart rate(HR) and Peak Systolic Velocity (PS).

The Carnation series Diagnostic Ultrasound System also include the function of wiScan, wiShow, wiGuide and wiNerve. wiScan is an easy-to-use quality assurance and workflow tool that automatically guides the user through an exam to ensure required steps are performed while reducing key strokes. wiShow is a teaching video recording software, which is an independent functional module integrated in the ultrasound diagnostic system. The function enables doctors to record and edit teaching videos, and export the video to a U disk or network storage. wiGuide uses the characteristics of the magnetic field to enhance the visualization effect of the needle by detecting the magnetized needle, and can better detect the position of the needle when it is in the human body. wiNerve is an education purpose tool, which aims to automatic recognition of different anatomical structures and display the recognized anatomical structures in different colors, to help doctors to improve the skills. The results of wiNerve are not used as diagnostic evidence.

Eight models for the main units are included in this submission, that is Carnation, Carnation Fast, Carnation T, Carnation Exp, Carnation Neo, Carnation+, Carnation Pro, Carnation Ultra. There are thirteen different models of probes: C6-1B-H, C6-2-H, C8-3-H, C9-3-H, EV11-3-H, L15-4WB-H, L15-4NB-H, L15-6-H, L22-10-H, L8-3-H, SP5-1-H, P8-3-H and P12-4-H are available for the Carnation series.

5. Indications for use

The 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 and superficial), cardiac (adult and pediatric), peripheral vessel, urology, Thoracic/Pleural, Vascular Access exams.

The Carnation series Diagnostic Ultrasound System is a general purpose diagnostic ultrasound system for use by qualified healthcare professionals. The clinical environments where the Carnation series can be used include critical care and emergency room environments, as well as point-of care areas in offices, clinical and hospital settings for diagnosis of patients.

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(TDI), Anatomic M-mode(AMM), Color M Mode(CM), Panoramic Imaging(PANO), and combined mode.

6. Comparison with Predicate Devices

Carnation series Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Device Name	510(k) Control 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.	Clivia series Diagnostic Ultrasound System	K211886

Carnation 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 as the predicate device Venue (K180599), except for Holo PW and PANO(panoramic imaging). For Holo PW, it has been cleared in reference device (K211886). For PANO(panoramic imaging), it can be considered same as reference device (K173471);

- The proposed device has the same function, except for wiGuide. The wiGuide 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 (K211886).

- The proposed device has the same function, except for wiNerve, it can be considered same as reference device (K211886).
- The proposed device has similar Ports as the predicate device Venue (K180599).
- The proposed device has similar Peripheral devices as the predicate device Venue (K180599), except for Magnetic cup and Foot switch. For Magnetic cup and Foot switch, it has been cleared in reference device (K211886).
- 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.

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

7. Non-clinical data

The following non-clinical data were provided in support of the substantial equivalence determination.

7.1 Biocompatibility testing

The biocompatibility evaluation for the Carnation 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 biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Skin Irritation

7.2 Electrical safety and electromagnetic compatibility (EMC)

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

7.3 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.

7.4 Acoustic testing

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

7.5 Clinical study

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

7.6 Animal Study

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

8. Conclusion

The differences between the Carnation 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 Carnation series Diagnostic Ultrasound System should perform as intended in the specified use conditions and conform to applicable medical device safety standards.

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