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

Re: K191347
Trade/Device Name: Paragon XHD 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: January 4, 2020
Received: January 9, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191347

Device Name
Paragon XHD Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound System is applicable for adults and pediatric patients. It is intended for use in pediatric, small organ (breast, thyroid, testicles, prostate), musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and dermatological exams.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K191347

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

1. Identification of Sponsor

Shenzhen Wisonic Medical Technology Co., LTD.

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

Contact Person: Jiang Xiaosan

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Fax: (+86)755 86007799

Date prepared Jan 30, 2019

2. Identification of Proposed Device

Device Name:	Paragon XHD Diagnostic Ultrasound System
Common/Usual Name:	Diagnostic Ultrasound System
Regulation number:	21 CFR 892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Regulation Class:	Class II
Product Code:	IYN, ITX, IYO
Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic
Model:	Paragon XHD

3. Identification of Predicate Device

Primary Predicate Device:

K160674, FUJIFILM SonoSite Vevo MD Imaging System

Secondary Predicate Device:

K163712, Clover 50/Clover60/Clover70 Diagnostic Ultrasound System

4 Device Description

The Paragon XHD Diagnostic Ultrasound System is a mobile software controlled ultrasonic system. Its function is to acquire and display ultrasound data in B-Mode, Color Flow Doppler, Power/Dirpower mode or the combination of these 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 Paragon XHD Diagnostic Ultrasound System consists of the main unit, an ultrasound probe, power adapter, connecting cable.

5. Intended Use

The Diagnostic Ultrasound System is applicable for adults and pediatric patients. It is intended for use in pediatric, small organ (breast, thyroid, testicles, prostate), musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and dermatological exams.

6. Substantial Equipment

The Paragon XHD Diagnostic Ultrasound System is comparable with and substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
Primary Predicate	FUJIFILM SonoSite	Vevo MD	K160674
Secondary Predicate	Wisonic	Clover 50/Clover60/Clover70	K163712

Compared of indications：

Indications of the predicate device (FUJIFILM SonoSite /Vevo MD/K160674) and the subject device (WISONIC/Paragon XHD) are the same.

Compared of Technological Characteristics:

The proposed device has the similar type probes and similar technical characteristics, including design, operation controls, display modes, operation modes, measurement items and image parameters as the predicate device Vevo MD(K160674).

The proposed device has the same connector port as the predicate device Clover 50/Clover 60/Clover 70(K163712).

The proposed device has the same capability in term of measurements and calculation functions as predicate device, except for adding area (ellipse, circle), angle and volume measurements in B-mode, C-mode, PW-mode and combined mode, and velocity in PW-mode. These measurements are substantially equivalent with the predicate device Clover 50/Clover 60/Clover 70(K163712).

The acoustic power level of proposed device Paragon XHD is below the limit of FDA, which is the same as the predicated device Clover 50/Clover 60/Clover 70(K163712).

All the above differences in technological characteristics do not rise 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.

Biocompatibility testing

The biocompatibility evaluation for the Paragon XHD Diagnostic Ultrasound System was conducted in accordance with the International Standard ISO 10993-1:2009/ (R)2013, "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

The ultrasonic probes and glue of the Diagnostic Ultrasound System are considered to contact directly with human body for a duration of less than 24 hours. The test results of cytotoxicity, sensitization and skin irritation complied with ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. It demonstrates substantial equivalences to the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Diagnostic Ultrasound System. The device complies with the IEC 60601-1:2005/A1:2012, standard for safety and the IEC 60601-1-2:2014, standard for EMC. It demonstrates substantial equivalences to the predicate device.

Performance testing

The Diagnostic Ultrasound System, was tested according to IEC 60601-2-37:2015 Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, and met the same standard, Performance testing was conducted on the Paragon XHD Diagnostic Ultrasound System, to evaluate the clinic measurement accuracy and system sensitivity, and all of the tested parameters met the predefined acceptance criteria. The comparisons of performance of Paragon XHD Diagnostic Ultrasound System to predicate devices are listed in the table below.

The performance of the device was compared with the predicate devices, and it is concluded that the proposed device is substantially equivalent to the predicate device.

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, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. It demonstrates substantial equivalences to the predicate device.

Animal Study

The subject of this premarket submission, the Paragon XHD Diagnostic Ultrasound System, does not require animal studies to support substantial equivalence.

8. Clinical data

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

9. Conclusion

The non-clinical data support the safety of the device and the performance testing report demonstrate that the Paragon XHD Diagnostic Ultrasound System should perform as intended in the specified use conditions and conform to applicable medical device safety standards. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification. Shenzhen Wisonic concludes that the Paragon XHD Diagnostic Ultrasound System is as safe and as effective as the predicate devices.