April 3, 2025

Carbon (Shenzhen) Medical Device Co., Ltd.
% Yuling Chen
Regulatory Affairs
Linnwell International Certification Consulting Co., Ltd.
First Floor, Building 1, No. 333 Wanfang Road,
Minhang District
Shanghai, 201112
CHINA

Re: K243298
Trade/Device Name: Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro 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: March 4, 2025
Received: March 4, 2025

Dear Yuling Chen:

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.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243298

Device Name
Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System

Indications for Use *(Describe)*
Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System is applicable for adults. It is intended for use in abdominal, superficial organs, trans-rectal, musculo-skeletal, peripheral vessel, urology exams. Modes of operation include: B, B+C, B+C+D(PW), B+M Mode, Image fusion, Needle Line.
This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display of the human body and fluid, which is intended to be used in a hospital or medical clinic.

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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510(k) Summary K243298

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR 807.92.

1.Submitter Information

Manufacturer	Carbon (Shenzhen) Medical Device Co., Ltd. Address: Room 203, Building B, 5# Skyworth Innovation Vally, No. 1 Tangtou Road, Tangtou Community, Shiyan Street, Bao'an District, 518102 Shenzhen, PEOPLE'S REPUBLIC OF CHINA Postcode: 518102
Contact Person	Yuling Chen Linnwell International Certification Consulting Co., Ltd. Email: Yuling.chen@linnwell.com Phone: +86 15021397762
Date Prepared	March 3, 2025

2.Device Information

Trade/Device Name	Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System
Proprietary Name	Ultrasonic pulsed doppler imaging system
Models	System: Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Probes: C5-2/R30-B, C3.5/R60-B, HL7.5/L40-B, FCL8-4-B
Regulation Number	21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN) 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO) 21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)
Regulation Name	Ultrasonic pulsed doppler imaging system
Product Code	IYN/IYO/ITX
Regulatory Class	II
Panel	Radiology

3.Predicate Device

Product name	Diagnostic Ultrasound System
Trade name	Resona R9S Probe: SC6-1U , C6-2GU, L11-3U, ELC13-4U
510(k) Number	K202785
Regulation number	21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN) 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO) 21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)
Regulation Name	Ultrasonic pulsed doppler imaging system
Regulation Class	II
Product Code	IYN/IYO/ITX
Manufacture	Shenzhen Mindray Bio-Medical Electronics Co.,LTD

4.Indications for Use

Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System is applicable for adults. It is intended for use in abdominal, superficial organs, trans-rectal, musculo-skeletal, peripheral vessel, urology exams.

Modes of operation include: B, B+C, B+C+D(PW), B+M Mode, Image fusion, Needle line.
This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display of the human body and fluid, which is intended to be used in a hospital or medical clinic.

5.Device Description

Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System is a medical, real-time, high-resolution ultrasound diagnosis system. It has a 24" multi-directional swiveled (non-touch) LCD monitor, a secondary 17" touch-display and cart. The System offers B, C, D, M Mode, as well as FUSION Mode which could synthesis real-time US images and preoperative images, such as CT and MRI. It could be equipped with convex-array, linear-array and intracavitary tracked probes, that supporting a wide range of clinical applications.

6.Comparison to predicate device

- Subject device Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System is comparable with substantially equivalent to these predicate device mentioned in 3. Predicate Devices with regards to intended use, imaging modes, functions and technological characteristics.

Items	**Subject device** **Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro**	**Predicate device** **Resona R9S**	**Comparison**
Indications for use	The System is applicable for adults. It is intended for use in abdominal, superficial organs, trans-rectal, musculo-skeletal, peripheral vessel, urology exams.	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel, urology exams.	SE The subject devices are not intended to use in obstetrics, vascular, nerves, fetal, cephalic, cardiac, trans-esoph, thoracic/pleural，transvaginal. The indications for use in abdominal, superficial organs, trans-rectal, musculo-skeletal, peripheral vessel, urologyare same. The subject devices is not intended to combination use with probes in obstetrics, vascular, nerves, fetal, cephalic, cardiac, trans-esoph, thoracic/pleural, transvaginal. The differences will not generate negative effects of safety and effectiveness to the indications in abdominal, superficial organs, trans-rectal, musculo-skeletal, peripheral vessel, urology, so that both are substantial equivalent.
	This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.	This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.	
Image	Modes of operation include: B	Modes of operation include: B,	SE

Modes	Mode, B+C Mode, B+C+D（PW） Mode, B+M Mode, Tissue Harmonic lmaging	M, PWD (Pulse wave Doppler), CWD (Continuous wave Doppler), Color Doppler, Amplitude Doppler, Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Smart 3D, 4D (Real-time 3D), iScape View, TDI (Tissue Doppler Imaging), Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO (Left Ventricular Opacification), V Flow (Vector Flow), STE (Sound Touch Elastography), STQ (Sound Touch Quantification), Contrast imaging (Contrast agent for Liver)	The subject device and the predicate device both feature B Mode, B + C Mode, B + C + D (PW) Mode, B + M Mode, Image Fusion, and Tissue Harmonic Imaging functions. The predicate device also includes Power + B and Power + PW + B functions, which are similarly available in the subject device. It is important to note that "Power" serves as a control parameter in the B + C and B + C + D (PW) modes and is not claimed as a separate function. Therefore, the subject device is considered equivalent to the predicate device.
Function	Image Fusion	Image Fusion	SE
	Needle line	Biopsy Guidance	SE

7. Non-Clinical Test

Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and this device has been designed to conform with applicable medical safety standards.

This device has been tested and evaluated under the following standards:

- 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)];
- IEC 60601-2-37:2007 + A1:2015 Medical electrical equipment - Part 2-37: Particular

requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment;

- IEC 60601-1-2:2014 +A1:2020 General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests;
- IEC 62359:2010+A1:2017/EN 62359:2011+A1:2018 Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment, Revision 3 NEMA UD 2-2004 (R2009);
- NEMA UD 2-2004 (R2009)Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment, Revision 3;
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems;
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;
- ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices;
- ISO 14971:2019 Medical devices - Application of risk management to medical devices;
- IEC 62304:2006/Amd 1:2015 Medical device software - software life cycle processes.

8. Clinical Studies

Not applicable. The subject of this submission,Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9.Summary

Based on the performance data as documented in the study, Venus Ultimate-Dual, Venus Ultimate-Hepa, Venus Ultimate-Uro Diagnostic Ultrasound System was found to have a safety and effectiveness profile that is similar to the predicate device.

10. Conclusion

The performance testing support that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.