August 30, 2024

Vave Health, Inc
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K241051
Trade/Device Name: Vave Wireless 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: August 26, 2024
Received: August 26, 2024

Dear Prithul Bom:

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,

Marjan Nabili -S for

Yanna Kang
Assistant Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241051

Device Name

Vave Wireless Ultrasound System

Indications for Use *(Describe)*

The Vave Wireless Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

The Vave Wireless Ultrasound System is intended to be used by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training.

The Vave Wireless Ultrasound System is a transportable system that is intended for use in environments where healthcare is provided by trained healthcare professionals (e.g., Hospital, clinic, medical office), home environment, road/air ambulance and other environments where healthcare is provided. The Vave Charger is to be used in a stationary setting.

It is indicated for diagnostic ultrasound imaging in the following applications: Ophthalmic, Fetal/ Obstetrics, Abdominal (includes Gynecology, Renal, and Urology), Pediatric, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Small Organ (includes Breast, Thyroid, and Scrotum), Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and procedural guidance of needles into the body. The operating modes are B mode, M mode, B+M, B+C, CD 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

510(k) Notification K241051

GENERAL INFORMATION

Applicant:

Vave Health, Inc.
3031 Tisch Way,
110 Plaza West
San Jose, CA
U.S.A. 95128
Phone: 510-366-2466

Contact Person:

Sandhya Mitnala
Sr. Director of Quality Assurance and Regulatory
Vave Health, Inc.
Phone: 510-366-2466
Email: sandhya@vavehealth.com

Date Prepared:

August 30th, 2024

DEVICE INFORMATION

Trade Name:

Vave Wireless Ultrasound System

Generic/Common Name:

Wireless Ultrasound System

Classification and Product Codes:

21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic pulsed Doppler imaging system.	IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	IYO
892.1570	Diagnostic Ultrasound Transducer	ITX

PREDICATE DEVICES

- Primary Predicate Device: Vave Personal Ultrasound (K191541)
- Reference Device: Clarius Ultrasound Scanner (K192107)

DEVICE DESCRIPTION

The Vave Wireless Ultrasound System is a handheld ultrasound imaging system consisting of the following components: Ultrasound Probe, Display Application, Battery, and Battery Charger.

The ultrasound probe (Model VA-0192), including its embedded software, is designed to acquire ultrasound image data and to wirelessly transmit the data to the display application software. The display application software runs on a commercial off-the-shelf mobile device. The operating system of the mobile device can be either iOS or Android. The ultrasound probe is completely wireless and is powered by a removable Li-ion battery (Model VA-0175). The battery is charged with a proprietary charging system (Model VCG).

CHANGES IMPLEMENTED

The present submission is an expansion based on the previous clearance - K191541. The subject device changes of this new submission are the addition of a new transducer model, the Vave Linear Array probe ("Vave Linear") with upgraded hardware to the Vave Wireless Ultrasound System. The Vave Phased transducer model and the clinical indications supported were cleared under K191541. The Vave Linear transducer model supports additional clinical indications as described in the Indications for Use for the Linear array probe, which are the same as the reference device Clarius Ultrasound Scanner (K192107). Appropriate changes have been made to mitigate risks and ensure the safety and effectiveness of these new features.

INTENDED USE/ INDICATIONS FOR USE

The Vave Wireless Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

The Vave Wireless Ultrasound System is intended to be used by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training.

The Vave Wireless Ultrasound System is a transportable system that is intended for use in environments where healthcare is provided by trained healthcare professionals (e.g., Hospital, clinic, medical office), home environment, road/air ambulance and other environments where healthcare is provided. The Vave Charger is to be used in a stationary setting.

It is indicated for diagnostic ultrasound imaging in the following applications: Ophthalmic, Fetal/Obstetrics, Abdominal (includes Gynecology, Renal, and Urology), Pediatric, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Small Organ (includes Breast, Thyroid, and Scrotum), Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and procedural guidance of needles into the body.
The operating modes are B mode, M mode, B+M, B+C, CD mode.

PRESCRIPTION STATUS

This is a prescription device. The prescription device statement appears in the labeling.

STERILIZATION SITE(S)

Not applicable. There are no components in the Vave Wireless Ultrasound System supplied sterile.

TRACK

The Vave Wireless Ultrasound System will be following Track 3 outlined in the FDA Guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued February 21, 2023.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The intended use including all indications for use of the Vave Wireless Ultrasound System are the same as the predicate device. The fundamental technology of the Vave Wireless Ultrasound System is the same as the primary (K191541) and reference (K192107). Vave Wireless Ultrasound System introduces no new indications for use, modes, features, or technologies relative to the predicate device. The Vave Wireless Ultrasound System is substantially equivalent to the predicate device.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The following table provides a detailed comparison of the intended use, indications for use and the device specifications between the subject device (Vave Wireless Ultrasound system) and the predicate and reference devices. All indications for use introduced by the subject device are similar to predicate and the reference device.

Comparison Parameter		Subject Device: Vave Wireless Ultrasound System	Primary Predicate: Vave Personal Ultrasound System (K191541)	Clarius Ultrasound Scanner (K192107)
Intended Use		The Vave Probe is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.	The Vave Probe is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging and fluid flow analysis
Indications for use	Ophthalmic	Yes	No	Yes
	Fetal/OB	Yes	Yes	Yes
	Abdominal	Yes	Yes	Yes
	Intra-operative (Abdominal organs and Vascular)	No	No	Yes
	Pediatric	Yes	Yes	Yes
	Small Organ (Thyroid, Scrotum, Breast)	Yes	No	Yes
	Adult Cephalic	No	No	Yes
	Trans-rectal	No	No	Yes
	Trans-vaginal	No	No	Yes
	Musculo-skeletal (Conventional)	Yes	No	Yes
	Musculo-skeletal (Superficial)	Yes	No	Yes
	Urology	Yes	Yes	Yes
	Gynecology	Yes	Yes	Yes
	Renal	Yes	Yes	No
	Thoracic/Pleural	Yes	Yes	No
	Cardiac adult	Yes	Yes	No
	Cardiac pediatric	Yes	Yes	No
	Peripheral vessel	Yes	Yes	Yes
	Carotid	No	No	Yes
	Needle Guidance	Yes	Yes	Yes

Comparison Parameter		Subject Device: Vave Wireless Ultrasound System	Primary Predicate: Vave Personal Ultrasound (K191541)	Reference device: Clarius Ultrasound Scanner (K192107)
Environment of Use	Professional	Yes	Yes	Yes
	Home	Yes	Yes	No
	Emergency Medical Services	Yes	Yes	No
510(k) Track		Track 3	Track 3	Track 3
Modes of Operation	B-Mode	Yes	Yes	Yes
	Color Doppler	Yes	Yes	Yes
	M-Mode	Yes	Yes	Yes
	Combined (B+CD)	Yes	Yes	Yes
Patient-Contacting Materials		All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible and can be disinfected
Principle/Method of Operation		Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.
Transducer Technology		Piezoelectric	Piezoelectric	Piezoelectric
Transducer Types	Phased Array	Yes	Yes	Yes
	Linear Array	Yes	No	Yes
	Convex Array	No	No	Yes
Probe Connection to Display		Wireless	Wireless	Wireless
	Image export	Yes	Yes	Yes
	Measurements	Yes	Yes	Yes
	Annotations	Yes	Yes	Yes
Portability		Portable Ultrasound System	Portable Ultrasound System	Portable Ultrasound System
Power Source		Removable battery (Li-ion)	Removable battery (Li-ion)	Removable battery (Li-ion)
Display		iOS or Android mobile device	iOS or Android mobile device	iOS or Android mobile device

Comparison Parameter		Subject Device: Vave Wireless Ultrasound System	Primary Predicate: Vave Personal Ultrasound (K191541)	Reference device: Clarius Ultrasound Scanner (K192107)
Wireless Capability		Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth
Cybersecurity	Data at rest	- 256-Bit AES - HTTPS TLS 1.2	- 256-Bit AES - -HTTPS TLS 1.2	- RSA256 - 128-Bit AES - HTTPS TLS 1.2
	Data in transit	- WPA2 (AES)	-WPA2 (AES)	- WPA2 (AES)
	User security	- Authentication services provided by Amazon Cognito; - Password reset tokens follow NIST standards. - NIST approved one-way cryptographic hash with salt	- Authentication services provided by Amazon Cognito; - Password reset tokens follow NIST standards. NIST approved one-way cryptographic hash with salt	- Two-factor authentication (Cloud only) - Passwords follow NIST standards

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Vave Wireless Ultrasound System to support a determination of substantial equivalence to the predicate device. The nonclinical testing conducted on the Vave Wireless Ultrasound System includes:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

- IEC 60601-2-37 Edition 2.1 2015 Medical Electrical Equipment - Part 2- 37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION

  Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62133-2 Edition1.0 2017-02 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 2: Lithium Systems
- ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]
- ISO 10993-1 Fifth Edition 2018-08 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

The collective results of the non-clinical testing demonstrate that the Vave Wireless Ultrasound System meets the established specifications necessary for consistent performance for its intended use.

SUMMARY OF CLINICAL TESTS

The Vave Wireless Ultrasound system introduces no new indications for use, modes, features or technologies relative to the predicate device that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

QUALITY ASSURANCE MEASURES

Quality assurance measures applied to the system design and development include, but are not limited to:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification and Validation

CONCLUSION

The Vave Wireless Ultrasound System is substantially equivalent to the identified predicate device. The Vave Wireless Ultrasound system has the same intended use and fundamental technological characteristics as the identified predicate device.