Vave Health, Inc.
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

July 10, 2019

Re: K191541
Trade/Device Name: Vave Personal Ultrasound
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 7, 2019
Received: June 11, 2019

Dear Mr. Job:

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 and Part 809); 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)*

K191541

Device Name
Vave Personal Ultrasound

Indications for Use *(Describe)*
The Vave Personal Ultrasound is intended for diagnostic ultrasound imaging in B-Mode.

It is indicated for diagnostic ultrasound imaging in the following applications: Fetal/Obstetric, Abdominal (includes Gynecology, Renal, and Urology), Pediatric, Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and procedural guidance of needles into the body.

The Vave Personal Ultrasound is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

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."

System: Vave Personal Ultrasound
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Other
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal/OB	N					
	Abdominal (1)	N					
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric	N					
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skeletal (Conventional)						
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Specify) (2)	N					
Cardiac	Cardiac Adult	N					
	Cardiac Pediatric	N					
	Intravascular (Cardiac)						
	Trans-esoph. (Cardiac)						
	Intra-cardiac						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel (3)	N					
	Other (Non-vascular) (4)	N					

Notes:
N = new indication; P = previously cleared by FDA; E = added under this appendix
(1) Abdominal includes Gynecology, Renal and Urology
(2) Other use includes Thoracic/Pleural detection of fluid and pleural motion/sliding
(3) Peripheral Vessel includes arteries and veins
(4) Non-vascular is image guidance for freehand needle/catheter placement

Device Name: Vave Phased VP3
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Other
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal/OB	N					
	Abdominal (1)	N					
	Intra-operative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric	N					
	Small Organ (Specify)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skeletal (Conventional)						
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Specify) (2)	N					
Cardiac	Cardiac Adult	N					
	Cardiac Pediatric	N					
	Intravascular (Cardiac)						
	Trans-esoph. (Cardiac)						
	Intra-cardiac						
	Other (Specify)						
Peripheral Vessel	Peripheral vessel (3)	N					
	Other (Non-vascular) (4)	N					

Notes:
N = new indication; P = previously cleared by FDA; E = added under this appendix
(1) Abdominal includes Gynecology, Renal and Urology
(2) Other use includes Thoracic/Pleural detection of fluid and pleural motion/sliding
(3) Peripheral Vessel includes arteries and veins
(4) Non-vascular is image guidance for freehand needle/catheter placement

510(K) SUMMARY

510(k) Notification K 191541

GENERAL INFORMATION

Applicant:

Vave Health, Inc.
2955 Campus Drive, Suite 110
San Mateo, CA
U.S.A.
Phone: (415)264 -5284

Contact Person:

Joseph Ko
Director of Quality Assurance and Regulatory
Vave Health, Inc.
Phone: (415) 264 -5284
Email: Regulatory@vavehealth.com

Date Prepared:

May 13, 2019

DEVICE INFORMATION

Trade Name:

Vave Personal Ultrasound

Generic/Common Name:

Ultrasound Imaging System

Classification:

Class II

Classification Name:

21 CFR Section	Classification Name	Product Code
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasonic Transducer	90 ITX

SUBSTANTIALLY EQUIVALENT DEVICES

- **Primary Predicate Device:** Vscan with Dual Probe (K140693)
- **Reference Device:** Clarius Ultrasound Scanner (K172385)

DEVICE DESCRIPTION

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

The ultrasound probe, 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. The battery is charged with a proprietary charging system.

The Vave Personal Ultrasound is intended for use in environments where healthcare is provided by healthcare professionals, including home healthcare environments and emergency medical services, ambulance, or aircraft environments.

INDICATIONS FOR USE

The Vave Personal Ultrasound is intended for diagnostic ultrasound imaging in B-Mode. It is indicated for diagnostic ultrasound imaging in the following applications: Fetal/Obstetric, Abdominal (includes Gynecology, Renal, and Urology), Pediatric, Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and procedural guidance of needles into the body.

The Vave Personal Ultrasound is a transportable ultrasound system that is intended for use in environments where healthcare is provided by healthcare professionals.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The intended use including all indications for use of the Vave Personal Ultrasound are the same as the primary predicate device (K140693). The fundamental technology of the Vave Personal Ultrasound is the same as the predicate (K140693) and reference (K172385) devices. Vave Personal Ultrasound introduces no new indications for use, modes, features, or technologies relative to the predicate devices. The Vave Personal Ultrasound is substantially equivalent to the predicate devices.

Comparison Parameter		**Subject Device:** Vave Personal Ultrasound	**Primary Predicate Device:** Vscan with Dual Probe with Transducer G3S (K140693)
Intended Use		Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for use	Fetal/OB	Yes	Yes
	Abdominal	Yes	Yes
	Intra-operative (Specify)	No	No
	Pediatric	Yes	Yes
	Small Organ	No	No
	Neonatal Cephalic	No	No
	Adult Cephalic	No	No
	Musculoskeletal (Conventional)	No	No
	Musculoskeletal (Superficial)	No	No
	Urology	Yes	Yes
	Gynecology	Yes	Yes
	Renal	Yes	Yes
	Thoracic/Pleural	Yes	Yes
	Cardiac adult	Yes	Yes
	Cardiac pediatric	Yes	Yes
	Fetal echo	No	No
	Peripheral vessel	Yes	Yes
	Carotid	No	No
	Needle Guidance	Yes	Yes
Environment of Use	Professional	Yes	Yes
	Home	Yes	No
	Emergency Medical Services	Yes	No
510(k) Track		Track 3	Track 3
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
Transducer Technology		Piezoelectric	Piezoelectric
Transducer Types	Phased Array	Yes	Yes
	Linear Array	No	Yes
	Convex Array	No	No

Comparison Parameter		Subject Device: Vave Personal Ultrasound	Primary Predicate Device: Vscan with Dual Probe with Transducer G3S (K140693)
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.
Modes of Operation	B-Mode	Yes	Yes
	Color Doppler	No	Yes
	M-Mode	No	No
	Combined (B+CD)	No	Yes

SUMMARY OF NONCLINICAL TESTING

All necessary performance testing was conducted on the Vave Personal Ultrasound to support a determination of substantial equivalence to the predicate devices. The nonclinical testing conducted on the Vave Personal Ultrasound 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 4.0 2014-02 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 2.0 2015-01 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 1.0 2014-06 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 1.0 2015-02 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)]
- 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 Personal Ultrasound meets the established specifications necessary for consistent performance for its intended use.

SUMMARY OF CLINICAL TESTING

The Vave Personal Ultrasound introduces no new indications for use, modes, features or technologies relative to the predicate devices 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 Personal Ultrasound is substantially equivalent to the identified predicate devices. The Vave Personal Ultrasound has the same intended use and fundamental technological characteristics as the identified predicate devices.

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 Personal Ultrasound supplied sterile.

TRACK

This is a Track 3 system.