



July 19, 2024

CorVascular Diagnostics, LLC
% Paul Dryden
President
ProMedic Consulting, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K233976
Trade/Device Name: VasoGuard (V10, V8, V6, V4, V2)
Regulation Number: 21 CFR 870.2880
Regulation Name: Ultrasonic transducer
Regulatory Class: Class II
Product Code: JOP
Dated: June 19, 2024
Received: June 20, 2024

Dear Paul Dryden:

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.

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,
for **Hetal B. Odobasic -S**
LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
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.

510(k) Number (if known)

K233976

Device Name

VasoGuard (V10, V8, V6, V4, V2)

Indications for Use (Describe)

The VasoGuard devices are intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. The devices are not intended to replace other means of evaluating vital patient physiological testing, are not intended to be used in neonatal applications, and are not intended to be used inside the sterile field. The intended use by qualified and trained medical professionals in hospitals, clinics, and physician offices by prescription or on the order of a medical doctor.

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

Submission Type

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21CFR Part 807.92.

Device Name

VasoGuard® V10, V8, V6, V4, V2

Owner/Submitter

807.92(a)(1)

Company Name: CorVascular Diagnostics, LLC
600 Twelve Oaks Center Drive, Suite 102
Wayzata, MN 55391
Telephone: (763) 333-1540
Contact Person: Spencer Lien
Contact Title: Managing Director
Preparation Date: December 8, 2023

Device Name

807.92(a)(2)

Device Trade Name: VasoGuard V10, V8, V6, V4, V2
Common Name: CW Doppler, PPG, VPR / PVR
Classification Name: Transducer, Ultrasonic
Regulation Number: 21 CFR 870.2880
Product Code: JOP
Class: Class II
Review Panel: Cardiovascular

Substantial Equivalence

807.92(a)(3)

510(k):	K111416
Trade Name:	Falcon/Pro, Falcon/Quad, Falcon/ABI+
Company Name:	Viasonix Ltd

Device Description

807.92(a)(4)

The VasoGuard is a family of products designed for non-invasive peripheral vascular diagnostic testing. It uses Doppler probes and photoplethysmography (PPG) sensors positioned on the body to measure physiologic signals and report data to the interpreting clinician. The system consists of up to 10 independent pneumatic pressure channels, up to five PPG ports, up to three Doppler ports that support 4MHz and 8MHz continuous wave (CW) Doppler probes, and a touchless temperature sensor. The V series indicates the products are all made from the same parts with the only differences being that certain parts are not installed when assembled during manufacturing or some features are not enabled.

The VasoGuard family consists of five different configurations of the same device, each varying in the number of pressure channels and sensor ports accessible through one of two available enclosures. The Full-Size enclosure supports Models V6, V8 and V10, and the Mini enclosure supports Models V2 and V4:

Model V10:	10 Pressure Channels / 5 PPG / 3 Doppler
Model V8:	8 Pressure Channels / 4 PPG / 2 Doppler
Model V6:	6 Pressure Channels / 4 PPG / 1 Doppler
Model V4:	4 Pressure Channels / 4 PPG / 1 Doppler
Model V2:	2 Pressure Channels / 2 PPG / 0 Doppler

All VasoGuard models contain the same main printed circuit board (PCB), manifold PCB(s), built-in power supply, built-in USB hub, and connect to a dedicated Windows-based medical grade PC via USB. Internally the models all utilize the same manifold assemblies and only differ in the quantity installed. The models include physical connections for control of 10 BP cuffs simultaneously, up to five PPG sensors simultaneously, one of up to three Doppler probes (4 MHz or 8 MHz), one USB camera, one IR remote control, and one touch-free infrared skin thermometer.

The two enclosures are made of the same aluminum material and share a common design. The Mini enclosure is approximately 20% smaller footprint. The Mini enclosure differs from the Full-Size enclosure only by the pressure channel connections on the front of the device instead of the back. Each model differs only in the number of pressure, Doppler and PPG ports on front and back panels of the device.

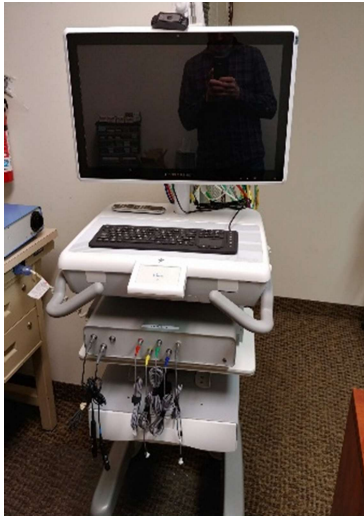
The VasoGuard software is pre-installed on the Windows PC. It controls all the models and automatically recognizes which model is connected thereby exposing only software capabilities only available on that model.

Each model includes certain components and accessories in addition to the VasoGuard device, including:

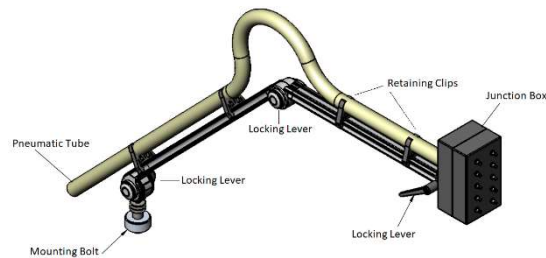
- Medical Grade Touchscreen PC
- Windows® 10 Enterprise LTSC
- Washable Keyboard with Trackpad
- Mobile Cart with Height-adjustable Rolling Cart
- Set of Pneumatic Hoses with Articulating Support Arm

- Set of Blood Pressure Cuffs (Shenzhen Vistar Medical Supplies Co., Ltd. K152468)
- Set of PPG Sensors
- Doppler Probes (4 MHz and/or 8 MHz)
- USB Camera
- Infrared Remote Control and Receiver
- Touch-free Infrared Skin Thermometer (Tecnimed SRL - 510(k) K122412)

VasoGuard V10 System



Pneumatic Hose and Articulating Support Arm



VasoGuard V10 Device – Front



VasoGuard V10 Device – Back



VasoGuard Device V10, V8, V6 Dimensions: 4"H x 16"W x 13"D

VasoGuard V4 Device – Front



VasoGuard V4 Device – Back



VasoGuard Device V4, V2 Dimensions: 4"H x 11"W x 12"D

VasoGuard Accessories



8 MHz Doppler
4 MHz Doppler
PPG (Red, Green, Yellow, Blue, Gray)
Remote Control
Temperature Meter



Blood
Pressure
Cuffs and
Tubing

The VasoGuard software features include patient database management; patient and exam search; importing and exporting of exams; facility management; importing and exporting of settings; exam protocol management, custom segment and vessel naming; customizable testing screens, reports, and graphs; backup and restore database; and keyboard shortcuts.

The quantitative measurements are the same for all VasoGuard models. One of the primary measurements is the Ankle Brachial Index (ABI). The ABI uses the Doppler probe to determine the ratio of the highest systolic pressure at the arm to the systolic pressure at the ankle. Systolic pressures are taken at both arms, and at the posterior tibial and dorsalis pedis arteries on each leg by inflating pressure cuffs past the point where Doppler sounds cease, then slowly deflating the cuffs until Doppler sounds return. The ABI is calculated by dividing the ankle pressure by the highest arm pressure.

Another primary measurement of the VasoGuard is segmental blood pressures. Segmental pressure studies are performed using the same method as an ABI but incorporate additional pressure cuffs wrapped at various positions on the leg. The software automatically places a cursor at the time location which is suspected as being the systolic pressure, yet it is the responsibility of the medical staff to modify the cursor location to define the correct segmental pressure.

Another main measurement of the VasoGuard is recording a waveform representing blood flow for each heartbeat. The system is capable of recording Doppler, PPG (photoplethysmography) and PVR (Pulse Volume Recording) waveforms. Each corresponds to the phases of the cardiac cycle, with a brisk upstroke and sharp peak that occur during systole, followed by a gradual downslope that occurs in diastole. A reflective wave, or dicrotic notch, represents reflected blood flow.

A high-level overview of continuous-wave (CW) Doppler is as follows. A CW Doppler transducer contains two piezoelectric elements: one to transmit the sound waves of constant frequency continuously and one to receive the echoes continuously. A single-element transducer cannot send

and receive at the same time. The sampling volume is restricted by the transmitted ultrasonic field (dependent on the frequency and focal properties of the sound beam) and the geometric arrangement of the elements. For the detection of a moving reflector located along the path of the transmitted beam, the resulting echo must strike the receiving crystal. The sensitive volume, or zone of sensitivity, is defined by the intersection of the transmitted ultrasound field and the reception zone. In essence then, each two-element transducer is focused to a particular depth. The two elements are tilted slightly to allow overlap between their respective fields of view (transmission and reception). The Doppler signal is amplified, filtered to remove unwanted low-frequency components caused by slow-moving structures such as vessel walls, and then routed to the speaker. The pitch of the audio output corresponds to the frequency shift between the transmitted and received sound waves and indicates the flow velocity within the vessel. As flow velocity becomes greater, a higher pitch is heard. A typical audio Doppler display for an artery exhibits a rhythmic rise and fall in the audible frequency due to the acceleration and deceleration of blood with systole and diastole.

A high-level overview of photoplethysmography (PPG) is as follows. PPG makes use of low-intensity infrared (IR) light. When light travels through biological tissues it is absorbed by bones, skin pigments and both venous and arterial blood. Since light is more strongly absorbed by blood than the surrounding tissues, the changes in blood flow can be detected by PPG sensors as changes in the intensity of light. The voltage signal from PPG is proportional to the quantity of blood flowing through the blood vessels. The PPG waveform comprises a pulsatile ('AC') physiological waveform attributed to cardiac synchronous changes in the blood volume with each heartbeat, and is superimposed on a slowly varying ('DC') baseline with various lower frequency components attributed to respiration, sympathetic nervous system activity and thermoregulation.

A high-level overview of pulse volume recording (PVR) is as follows. A PVR is a graph of the pulsatile change in limb volume from blood flow using constant standard pressure. Users acquire these tracings using the same pressure cuffs used for segmental limb pressure measurement. Normal PVRs consist of a rapid upstroke with a sharp peak, a dicrotic notch, and a concave-up late diastolic component. A reduced amplitude from trough to peak has been used as a criterion for diagnosing vascular claudication. Abrupt changes in amplitude and contour can indicate occlusion between the two levels.

Indications for Use

807.92(a)(5)

The VasoGuard devices are intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. The devices are not intended to replace other means of evaluating vital patient physiological testing, are not intended to be used in neonatal applications, and are not intended to be used inside the sterile field. The intended use by qualified and trained medical professionals in hospitals, clinics, and physician offices by prescription or on the order of a medical doctor.

Summary of Technological Characteristics Compared to Predicate

807.92(a)(6)

Feature	Falcon/Pro, Falcon/Quad, Falcon/ABI+	VasoGuard V2, V4, V6, V8, V10	Diff
510(k) Number	K111416	This application	
Classification	JOP	JOP	
Date	July 15, 2011	Pending	
Manufacturer	Viasonix Ltd	CorVascular Diagnostics, LLC	
Indications for use	The Falcon/Pro, Falcon/Quad, Falcon/ABI+ are intended for use in the noninvasive evaluation of peripheral vascular pathology in patients. The devices are not intended to replace other means of evaluating vital patient physiological processes, are not intended to be used in fetal applications, and are not intended to be used inside the sterile field. They are to be used by trained medical personnel in hospitals, clinics and physicians offices by prescription or doctor's orders.	The VasoGuard devices are intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. The devices are not intended to replace other means of evaluating vital patient physiological testing, are not intended to be used in neonatal applications, and are not intended to be used inside the sterile field. The intended use is attended use by trained medical professionals in hospitals, clinics, and physician offices by prescription or on the order of a medical doctor.	
Auto cuff inflation	Yes	Yes	
Pressure channels	4, 4, 10	2, 4, 6, 8, 10	(1)
Simultaneous PVR measurements	4, 4, 10	2, 4, 6, 8, 10	(2)
PPG sensors	4, 4, 5	2, 4, 4, 4, 5	
Doppler probes	4, 8 and 10 MHz CW	4 and 8 MHz CW	(3)
Doppler ports	0, 3, 3	0, 1, 1, 2, 3	
Skin temperature measurement	Yes, wired (auto)	Yes, touchless (manual)	(4)
Remote control operation	Yes, wired	Yes, (infrared)	(5)
Touchscreen controls	Yes	Yes	
Foot switch controls	Yes	No	(6)
Mouse and keyboard controls	Yes	Yes	
Control of target inflation pressures	Yes	Yes	
Control of pressures deflation rate	Yes	Yes	
Acoustic testing	Track 1	Track 1	
Max Ispta.α 4 MHz	691 mW/cm ²	366 mW/cm ²	(7)
Max Ispta.α 8 MHz	662 mW/cm ²	306 mW/cm ²	(7)
Doppler spectral analysis	256 FFT	256 FFT	
Bidirectional Doppler invert function	Yes	Yes	
Doppler volume controls	Yes	Yes	
Doppler envelope	Upper, lower, both, none	Upper, lower, both, none	(8)

Doppler, PVR, segmental pressure, exercise, venous reflux, Raynauds, TOS testing	Yes	Yes	
Complete System Tested to IEC 60601	No	Yes	(9)

The technical characteristics differences listed in the “Diff” column in the table above were compared to determine if any different issues of safety and/or efficacy exist. Upon review it was determined no safety or efficacy issues exist and no different questions of safety and effectiveness were raised. The differences listed do not constitute a new intended use.

Non-Clinical Testing

807.92(b)(1)

The VasoGuard (V10, V8, V6, V4, V2) range of non-invasive peripheral vascular diagnostic systems have been subjected to Biocompatibility, Acoustic Output, EMC Emissions and Immunity, Environmental Exposure, RFID Immunity, Electrical Safety, Performance, and Mechanical Safety testing by certified laboratories to ensure the devices comply with applicable industry and safety standards. Internally the VasoGuard has been subjected to unit, design verification, performance, accelerated aging, and validation testing to ensure the devices meet all their functional requirements and specifications.

Bench testing with the predicate device using simulators and live signals was conducted to ensure comparable waveform quality, sensitivity, and accuracy of reported values. The VasoGuard was found to be substantially equivalent to the predicate in all functions and parameters evaluated.

Conclusions

807.92(b)(3)

The conclusion drawn from these tests is that the VasoGuard V10, V8, V6, V4, V2 range of non-invasive peripheral vascular diagnostic systems are equivalent in safety and efficacy to the predicate devices listed in the comparison table above.