510(k) SUMMARY

FEB 12 2014

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number:	3005467960
Address of Manufacturer:	2014 Ford Road, Unit G Bristol, PA 19007
Contact Person:	James Gunnerson President
Date Prepared:	December 20, 2013
Trade or Proprietary Name:	PhysioFlow Q-Link
Common or Usual Name:	Noninvasive hemodynamic monitor
Classification Name:	Impedance plethysmograph (21 CFR 870.2770) Product code: DBS (plethysmograph, impedance) Class II
Predicate Device Identification:	PhysioFlow Enduro Model PF07 (K103283)

Device Description:

The PhysioFlow Q-Link is a noninvasive, hemodynamic monitor that utilizes thoracic electrical bioimpedance technology to measure cardiac output and related cardiac parameters. It consists of a small, portable, lightweight electronic unit that attaches to the patient via a six lead, patient cable using commercially available silver/silver chloride skin electrodes. Monitor data is transmitted to a host computer running the PhysioFlow PF107 software. Communication to the

host computer is via USB wired technology. The PhysioFlow PF107 software performs multiple tasks including signal processing and analysis, measured parameter computation, user interface display and control, measurement process control, event marker management, and output display/report generation. Available accessories include the patient and USB cables.

Indications for Use:

Indicated for use in adults only.

The PhysioFlow Q-Link noninvasively measures cardiac output and other related cardiac parameters. These parameters include:

CI	Cardiac Index
CO	Cardiac Output
CTI	Contractility Index
dZ / dt max	Maximum value dZ / dt
EDV	End Diastolic Volume
EF	Ejection Fraction
HR	Heart Rate
LCWI	Left Cardiac Work Index
PEP	Pre-Ejection Period
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
TFI	Thoracic Fluid Index
VET	Ventricular Ejection Time
Z0	Base Impedance

The PhysioFlow Q-Link is intended for use under the direct supervision of a licensed healthcare practitioner or personnel trained in its proper use within a hospital or facility providing healthcare.

Intended use and comparison to predicate devices:

The PhysioFlow Q-Link and PhysioFlow Enduro Model PF-07 have the same intended for use/indications for use. Both devices are intended for use in adults only to noninvasively measure cardiac output and other related cardiac parameters, including the following: cardiac output, cardiac index, contractility index, maximum value dZ/dt, end diastolic volume, ejection fraction, heart rate, left cardiac work index, pre-ejection period, stroke volume, systemic vascular resistance, systemic vascular resistance index, thoracic fluid index, ventricular ejection time, and base impedance. Both devices are intended for use under the direct supervision of a licensed

practitioner or personnel trained in its proper use within a hospital or facility providing healthcare.

Technological characteristics and comparison to predicate devices:

The PhysioFlow Q-Link is a modification of the PhysioFlow Enduro Model PF-07. It utilizes the same thoracic electrical bioimpedance technology to measure the same cardiac output and related cardiac parameters. It remains similar to the predicate device in size, but excludes the battery power source, on-board data storage, and wireless Bluetooth technology features of the predicate device. The PhysioFlow Q-Link will fill a position amongst the PhysioFlow family of devices for users who find the battery life or wireless communication features of the PhysioFlow Enduro Model PF-07 to be inconvenient or cumbersome, but still desire a small, portable unit. Like the PhysioFlow Enduro Model PF-07, the PhysioFlow Q-Link continues to interface with a MS Windows based host computer running the previously-cleared PhysioFlow PF107 software (K103283). No changes to the PhysioFlow PF107 software were required to enable its use with the PhysioFlow Q-Link.

The differences in technological characteristics between the subject and predicate devices do not raise new types of safety or effectiveness questions. Accepted scientific methods, such as performance (bench) testing, do exist for assessing the effect of the differences in characteristics.

Summary of performance data:

Design verification tests were performed on representative samples of the PhysioFlow Q-Link as a result of a comprehensive product development and risk management plan. All tests were verified to meet the pre-specified acceptance criteria. As such, the PhysioFlow Q-Link is considered substantially equivalent to the PhysioFlow Enduro Model PF-07.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 12, 2014

Vasocom, Inc.
Mr. James Gunnerson
President
2014 Ford Rd., Unit G
Bristol, PA 19007 US

Re: K140102
Trade/Device Name: Physioflow Q-link
Regulation Number: 21 CFR 870.2770
Regulation Name: Noninvasive Hemodynamic Monitor
Regulatory Class: Class II (two)
Product Code: DSB
Dated: January 14, 2014
Received: January 15, 2014

Dear Mr. James Gunnerson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: PhysioFlow Q-Link

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Digitally signed by Owen P. Faris -S
Date: 2014.02.11 16:04:51 -05'00'