510(k) SUMMARY

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

Establishment Registration Number:	3005467960
	DEC - 3 2010
Address of Manufacturer:	2014 Ford Road, Unit G Bristol, PA 19007
Contact Person:	James Gunnerson President
Date Prepared:	Oct. 26, 2010
Trade or Proprietary Name:	PhysioFlow Enduro Model PF07
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 System Model PF05 (K060387)

Device Description:

The PhysioFlow Enduro Model PF07 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 (less than 250 gm with batteries)

electronic unit that attaches to the patient via a six lead, patient cable using commercially-available silver/silver chloride skin electrodes. The electronic unit incorporates recorder capabilities, enabling it to capture and store up to 24 hours of monitor data for later transmission to a host computer running the PhysioFlow PF107 software. Communication options include Bluetooth wireless and 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 cable, a Bluetooth antenna, USB cable, and electronic unit carrying case.

Intended use and comparison to predicate devices:

The PhysioFlow Enduro PF07 and PhysioFlow System Model PF05 have the same intended use/indications for use. Both devices are intended for use in adults only to noninvasively measures 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.

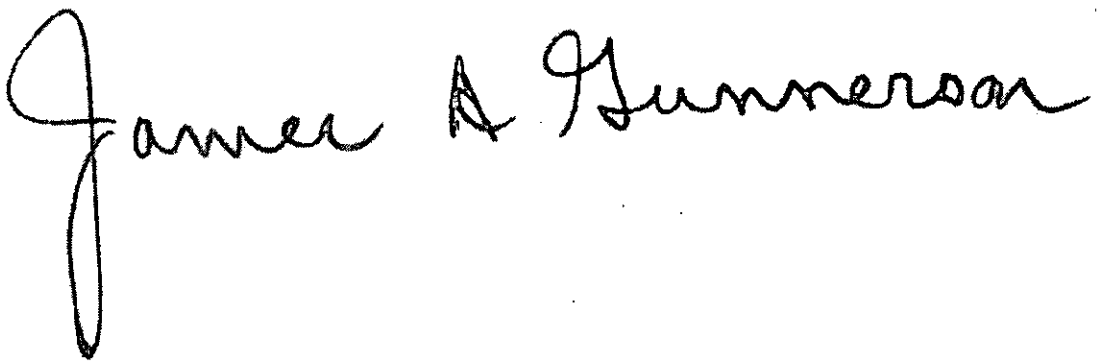
Technological characteristics and comparison to predicate devices:

The PhysioFlow Enduro Model PF07 is a modification of the PhysioFlow System Model PF05. It utilizes the same thoracic electrical bioimpedance technology to measure the same cardiac output and related cardiac parameters, but its size has been reduced to make it portable and lightweight (less than 250 gm with batteries). Compared with the Model PF05, technological changes also now enable the use of battery power and communication using Bluetooth wireless and USB wired technology with a MS Windows based host computer running an upgraded version of the PF05 software (i.e., PhysioFlow PF107). In addition, software and hardware changes now enable a standalone recorder capability, enabling of up to 24 hours capture of monitor data for later transmission to the host PC. Use of the same silver/silver chloride skin electrodes (Skintact FS-50 Pre-gelled Electrodes) is recommended.

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 Enduro Model PF07 and PhysioFlow PF107 software as a result of a comprehensive product development and risk management plan. All tests were verified to meet the pre-specified acceptance criteria. Product validation tests were performed in a simulated use setting and compared subject and predicate device performance. The results demonstrate a difference between the subject and predicate devices of less than 4% across the measured parameters, which is below the acceptable clinical variability of 5%. As such, the PhysioFlow Enduro Model PF07 is considered substantially equivalent to the PhysioFlow System Model PF05.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

VasoCOM, Inc.
c/o Mr. James Gunnerson
President,
2014 Ford Road, Unit G
Bristol, PA 19007

DEC - 3 2010

Re: K103283
Trade/Device Name: PhysioFlow® Enduro Model PF07
Regulatory Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II (two)
Product Code: 74 DSB
Dated: October 27, 2010
Received: November 5, 2010

Dear Mr. 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.

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.

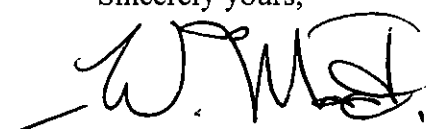
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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.htm for 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K103283

Device Name: PhysioFlow Enduro Model PF-07

DEC - 3 2010

Indications for Use:

Indicated for use in adults only.

The PhysioFlow Enduro PF07 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 Enduro System Model PF-07 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.

(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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103283