

H973059

DEC 17 1997

APPENDIX E

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR
VASOCOR PVR**

K973659

Submitter Vasocor
4001 N.W. 97th Avenue, Suite 101
Miami, Florida 33178
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Date summary was prepared: September 20, 1995

Name(s) of the device Vasocor PVR100

Identification of predicate device(s) Life Sciences Pulse Volume Recorder (preamendment and K832679)

Description of the device

The Vasocor PVR-100 provides Pulse Volume Recording (PVR) made possible through air plethysmography. The PVR-100 device, which is based on a PC platform, includes various standard blood pressure cuff sizes that allow use of the PVR measurement on various limb and digit extremities, a pneumatic circuit that allows for internal calibration as well as inflation cuff pressure, and a user interface that includes various menus and screens for inputting patient demographic data, performing tests, displaying and entering results, and printing reports. The PVR tracing is accomplished by attaching a standard blood pressure cuff on various areas of the extremities. Once atmospheric air is injected into the cuff to provide skin contact, a pressure transducer records the pressure change in the PVR cuff secondary to change in volume of the extremity segment under the cuff during repeated cardiac cycles. PVR measurement is accomplished by calculating the volume change in the extremity segment under evaluation, where the PVR tracing shows the change in pressure of the same segment during the cardiac cycle.

Intended Use

The Vasocor PVR-100 (Pulse Volume Recorder) is a non-invasive medical device used in conjunction with other devices such as; continuous-wave Doppler ultrasound, treadmill testing, and ultrasonic imaging techniques for vascular studies of limbs and digits. Use of the PVR in this manner allows the physician to non-invasively diagnosis extremity arterial and venous disorders.

Comparison of device characteristics to predicate

Table of Technological Characteristics			
Device Name	Vasocor PVR	Life Science PVR IV	Parks Medical Mini Lab VI
510(k) numbers	new submission	K832679	unknown
Indications for use	venous and arterial studies of limbs	same	same
Contraindications	none	same	same
Warnings / Precautions	prescription device	same	same
General Design	computer based, provides PVR tracings, includes pneumatic circuit, standard blood pressure cuffs and tubing	mechanical design, manual calibration	same as Life Sciences PVR IV
Features	Internal calibration, computer controlled, external printer, save patient data, print patient reports	built in strip chart printer, cannot print reports or save patient data	comes with either a built in strip chart recorder or a PC computer for record management and printing, or both
Gauges & Sensors	pressure transducer	pressure transducer	pressure transducer
Software	software control of patient records, tracings, and pneumatics	none	software control of patient records and tracings
Anatomical Site(s)	extremities and digits	same	same
Biocompatibility	blood pressure cuffs are standard marketed products are the same ones used by the Life Sciences PVR IV	same	similar

Non clinical testing:

A hemodynamic model of the arterial circulation in the lower extremity was developed specifically for the Vasocor PVR. The major feature of this model is that it produces Pressure and Volume contours that mimic the normal human circulation in lower extremities. By changing various parameters the operator can control hemodynamic variables. Flowrate, system compliance, and resistance to control pulse pressure and heart rate were varied in the in-vitro comparison testing. The major comparative parameter is the PVR amplitude and contour. Amplitudes were measured in millimeters to the nearest 0.5mm. Contour analysis were made by visual analysis (method used clinically).

Clinical testing:

Six subjects were evaluated using the new Vasocor PVR-100 subject to this 510(k) and the predicate device, the Life Sciences Pulse Volume Recorder. Three(3) normal subjects with no evidence of peripheral vascular disease and three(3) subjects with known peripheral vascular disease were selected for this comparison. Standard blood pressure cuffs were connected to the subjects. The cuffs were placed on upper arm, thumb, calf, and ankle for comparisons in both the normal subjects and subjects with known peripheral vascular disease.

Conclusion:

The Vasocor PVR is substantially equivalent to the Life Sciences Pulse Volume Recorder



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Jeff Raines, M.D., Ph.D.
Vasocor, Inc.
4001 NW 97th Avenue, Suite 101
Miami, FL 33178

DEC 17 1997

Re: K973659
Trade Name: Vasocor PVR 100
Regulatory Class: II
Product Code: 74JOM
Dated: September 5, 1997
Received: September 25, 1997

Dear Dr. Raines:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Jeff Raines, M.D., Ph.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number

None assigned as of this time

Device Name Vasocor PVR-100

Indications for Use

The Vasocor PVR-100 (Pulse Volume Recorder) is a non-invasive medical device used in conjunction with other devices such as; continuous-wave Doppler ultrasound, treadmill testing, and ultrasonic imaging techniques for vascular studies of limbs and digits. Use of the PVR in this manner allows the physician to non-invasively diagnosis extremity arterial and venous disorders.

Concurrence of CDRH, Office of Device Evaluation (ODE)

- Prescription Use (per 21 CFR 801.109)
- Over-the Counter Use

(Division Sign-Off) *[Signature]* 12/16/97
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973659