# Appendix 27

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

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

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 (Premarket 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.

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

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

# Appendix 28

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 1999

Jeff Raines Ph.D.
Vasocor, Inc.
Corporate Park of Miami
7705 N.W. 48th Street, Suite 120
Miami, FL 33166

Re: K990123
PVR-100/Vasogram
Regulatory Class: II
Product Code: JOM
Dated: January 13, 1999
Received: January 13, 1999

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 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). 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 (Premarket 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.

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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

## 8.0 Intended Use

In 510(k) K973889 for the Vasocor PVR-100 (Pulse Volume Recorder), the indications for use statement is as follows:

The PVR-100 is a noninvasive medical device used in conjunction with other devices such as: continuous-wave Doppler ultrasound, treadmill testing, and ultrasonic imaging techniques for vascular studies of the limbs and digits. Use of the PVR-100 in this manner allows the physician to noninvasively diagnosis extremity arterial and venous disorders.

The addition of the Vasogram to the PVR-100 expands the indications. The indications for use statement for the PVR-100 / Vasogram is given in its entirety as follows:

The PVR-100 / Vasogram is a noninvasive medical device used in conjunction with other devices such as: continuous-wave Doppler ultrasound, treadmill testing, and ultrasonic imaging techniques for vascular studies of the limbs and digits. Use of the PVR-100 / Vasogram in this manner allows the physician to noninvasively diagnosis extremity arterial and venous disorders, and receive, record, and produce a visual display of local arterial compliance.

Wolf Sepulveda MD
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990123

**Appendix 5**

After acquiring GMP and completing the Precision and Accuracy Studies the Company submitted its last 510(k) on May 22, 2001 (received May 25, 2001). The Trade Name was: Vascular Diagnostic Center Model 300. The FDA raised questions regarding this submission in a document dated August 22, 2001. The Company answered in an extensive documented dated October 29, 2001. This led to a substantially equivalent letter from the FDA (K011625). The Intended Use statement read as follows:

> The Vasocor Vascular Diagnostic Center (Model 300) is a non-invasive medical device that can be used by physicians and other health care professionals to measure blood pressure values (systolic, diastolic, and pulse pressure) and the heart pulse rates based on segmental measurement. The Vascular Diagnostic Center (Model 300) also calculated Framingham coronary heart disease, stroke, and peripheral disease risk scores, body mass index (BMI), ankle/brachial index (ABI), and pressure differentials between certain adjacent peripheral limb segments, and provides indication of arterial compliance. The indications of arterial compliance (that is, elasticity indices) can be used to assist in assessing and managing patients that may have potential underlying vascular disease, including cardiovascular disease that might require more specific diagnostic evaluations by physicians or other health care providers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2002



Mr. Walter M. Rosenbrough
President and Chief Executive Officer
Vasocor, Inc.
499 A Jessen Lane
Charleston, SC 29492

Re: K011625
Trade Name: Vascular Diagnostic Center Model 300
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 29, 2001
Received: October 31, 2001

Dear Mr. Rosebrough:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

**Indications for Use Statement**

**Premarket Notification [510(k)]:**

**Vasocor™ Vascular Diagnostic Center (Model 300)**

Indications for Use:

The Vasocor™ Vascular Diagnostic Center (Model 300) is a non-invasive medical device that can be used by physicians and other health care professionals to measure blood pressure values (systolic, diastolic and pulse pressure) and the heart pulse rates based on segmental measurement. The Vascular Diagnostic Center (Model 300) also calculates Framingham coronary heart disease, stroke, and peripheral disease risk scores, body mass index (BMI), ankle/brachial index (ABI), and pressure differentials between certain adjacent peripheral limb segments, and provides indications of arterial compliance. The indications of arterial compliance (that is, elasticity indices) can be used to assist in assessing and managing patients that may have potential underlying vascular disease, including cardiovascular disease, that might require more specific diagnostic evaluations by physicians or other health care providers.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011625