K011625
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JAN 2 3 2002

510(k) Summary

Premarket Notification [510(k)]:

Vasocor™ Vascular Diagnostic Center (Model 300)

1. **Submitter:** Vasocor, Inc.
499-A Jessen Lane
Charleston, SC 29492
843-284-4000
Fax: 843-849-1263
Contact: Walter M. Rosebrough, President and Chief Executive Officer

This summary was prepared on April 25, 2001 and revised October, 29, 2001.

2. **Proprietary Name:** Vasocor™ Vascular Diagnostic Center (Model 300)
Common Name: Vascular Laboratory
Classification Name: Non-invasive Blood Pressure Measurement System

3. **Statement of Equivalence**

The Vasocor™ Vascular Diagnostic Center (Model 300) is substantially equivalent to two cleared devices: (1) Touritu Engineering's MS-2000, K961144; and (2) Hypertension Diagnostics, Inc.'s CVProfilor DO-2020 CardioVascular Profiling System, K001948. All three products are non-invasive electronic devices that use the oscillometric method of blood pressure measurement to take various measurements; all three perform various calculations on the data collected, which are used to assess potential underlying vascular disease.

4. **Device Description**

The Vasocor Vascular Diagnostic Center (Model 300) is a vascular laboratory that integrates, into one device, various modules that provide indices of significance to peripheral vascular and cardiovascular function. These modules include Patient Data, Framingham and BMI, ABIgram™ Ankle/Brachial Index, PADogram™ Segmental Pressure Analysis, and Vasogram™ Arterial Compliance Procedure. The Vascular Diagnostic Center (Model 300) also offers administrative capabilities such as creating periodic system usage reports which show test dates, procedures performed, patient names, and physician names.

5. **Intended 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.

6. Technological Characteristics

Physically, the system consists of hardware and electronics housed in a cart with four wheels. The device includes a computer board, pneumatic circuit, monitor, keyboard, joystick, printer, tubing, blood pressure cuffs, and power cord. It also incorporates Colin Medical Instruments' oscillometric blood pressure module M1050, a standard high-end, off-the-shelf NIBP system which has passed UL and SP-10 testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 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.

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