DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 - 2004

CVP Diagnostics
c/o Dr. T. Whit Athey
The Health Policy Resources Group, LLC
Senior Consultant
2305 Gold Mine Road, Suite 200
Brookeville, MD 20833-2233

Re: K031327
Trade Name: VeriCor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: 74 DXN
Dated: March 31, 2004
Received: March 31, 2004

Dear Dr. Athey:

This letter corrects our substantially equivalent letter of May 12, 2004 regarding the classification of the subject device.

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 (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); 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 continue 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 Part 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for 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): K031327

Device Name: Vericor

Indications For Use:

The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic (LVEDP) pressure. This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected.

The device has been clinically validated in males only. Use of the device in females has not been investigated. Certain patient conditions should be considered as a basis for excluding individual patients for testing based on a possible risk to them of the Valsalva maneuver, such as the following:.

1. Weight <88 pounds (40 kilograms)*
2. Atrial flutter or atrial fibrillation with irregular ventricular response
3. Significant atrial or ventricular ectopy
4. Hypertrophic obstructive cardiomyopathy
5. History of paradoxical emboli
6. Known intracardiac shunt
7. Significant aortic valvular disease
8. Unstable angina
9. History of embolic CVA
10. Myocardial infarction within one week of intended VeriCor testing
11. Uncontrolled hypertension (systolic BP >160mmHg or diastolic BP $\geq$ 100mmHg)
12. Hypotension (systolic BP<90mmHg)
13. Symptomatic bradycardia
14. Known cholesterol emboli
15. Poor LV function with LV thrombus

*Colin tonometer recommendation

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochnowski

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031327

K031327

1/3

MAY 1 2 2004

510(k) Summary

VeriCor

Common/Classification Name: Diagnostic Intravascular Catheter, 21 CFR 870.1200

CVP Diagnostics
160 Commonwealth Ave; Suite 801
Boston, MA 02116

Contact: Kevin McIntyre, Prepared: September 9, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

The **VeriCor** is substantially equivalent to the Arrow Balloon Wedge Pressure Catheter, which is a pre-Amendments device. The VeriCor device incorporates two independent medical devices that were previously cleared by FDA: The W. E. Collins Airway Pressure Monitor was cleared by FDA as K912946, and the Colin CBM7000 Pulse Tonometer was cleared by FDA as K900247. The **VeriCor** is substantially equivalent to these two devices in regard to many of its technological characteristics.

B. DEVICE DESCRIPTION

The **VeriCor** device is intended to be used as one of several tools that will assist the cardiologist in assessment of the volume status of a patient, i.e., when the questions of either volume overload or volume depletion arises. A principal measure of intravascular volume status is the filling pressure in the left ventricle as best reflected by the left ventricular end-diastolic pressure (LVEDP). Measurement of the left ventricular end-diastolic pressure requires the placement of a catheter in the left ventricle of the heart to measure the pressures directly. This procedure involves a moderate risk to the patient but could result in arterial hemorrhage, stroke and death. Accordingly, it cannot be used as a routine procedure for patient assessment or for monitoring over time.

An estimate of LVEDP may be obtained with somewhat less risk to the patient by catheterization of the pulmonary artery as described above. The resulting measurement, called the Pulmonary Capillary Wedge Pressure (PCWP), correlates well with LVEDP. PCWP is widely used as an alternative to direct measurement of LVEDP, even though it has

potential for complications and limitations in accuracy that are recognized.

The proposed device, the **VeriCor**, is intended to provide another point on the risk/benefit curve for assessment tools. The **VeriCor** is non-invasive, so it involves much less risk than catheterization of either the left ventricle or the pulmonary artery. The **VeriCor** device provides measurements that are well correlated with PCWP measurements.

The Colin CBM7000 Pulse Tonometer and the W. E. Collins Airway Pressure Monitor each have an interface connection for a computer to read data from the devices. In the **VeriCor**, a computer reads data from these devices during a sequence of procedures with the patient, including the Valsalva maneuver, and, using a proprietary algorithm, converts the data to estimates of the left ventricular pressure.

The digital manometer is used to measure the airway strain of the patient blowing into the mouthpiece. The pulse tonometer provides an instantaneous and continuous measure of non-invasive blood pressure before, during and after the Valsalva manuever. Data are recorded from both devices so as to provide a baseline followed by a minimum of eight and a maximum of 15 seconds of modest expiratory strain which is followed by 15 to 20 seconds of post-strain recording. The computer controller acquires the data from the devices and provides a dialog with the health-professional user. The user coaches the patient to perform the necessary actions, and one or more practice sessions are used to ensure that the patient can perform those actions correctly.

C. INTENDED USE

The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic (LVEDP) pressure. This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected.

The device has been clinically validated in males only. Use of the device in females has not been investigated. Certain patient conditions should be considered as a basis for excluding individual patients for testing based on a possible risk to them of the Valsalva maneuver, such as the following:

1. Weight <88 pounds (40 kilograms)*
2. Atrial flutter or atrial fibrillation with irregular ventricular response
3. Significant atrial or ventricular ectopy
4. Hypertrophic obstructive cardiomyopathy
5. History of paradoxical emboli

6. Known intracardiac shunt
7. Significant aortic valvular disease
8. Unstable angina
9. History of embolic CVA
10. Myocardial infarction within one week of intended VeriCor testing
11. Uncontrolled hypertension (systolic BP >160mmHg or diastolic BP ≥ 100mmHg)
12. Hypotension (systolic BP<90mmHg)
13. Symptomatic bradycardia
14. Known cholesterol emboli
15. Poor LV function with LV thrombus

*Colin tonometer recommendation

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **VeriCor** is a medical device, and it has similar indications for use and target population as the legally marketed predicate device. The differences in indications statements do not change the intended diagnostic effect. The **VeriCor** has the same technological characteristics as two of the predicate devices, the W. E. Collins Airway Pressure Monitor (K912946), and the Colin CBM7000 Pulse Tonometer (K900247), though it has different technological characteristics from the primary predicate device. The different technological characteristics could affect the tradeoff between safety and effectiveness compared to the primary predicate device. However, no new safety and effectiveness issues are raised by the **VeriCor** device, and there are established scientific techniques for assessing the safety and effectiveness of the device. The performance testing carried out on the device assures substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The VeriCor device incorporates the technological characteristics of the two previously cleared component devices, the W. E. Collins Airway Pressure Monitor (K912946), and the Colin CBM7000 Pulse Tonometer (K900247)

F. TESTING

The results from clinical studies of the device are presented in the 510(k).

G. CONCLUSIONS

This 510(k) has demonstrated "substantial equivalence" as it is defined in the Federal Food, Drug, and Cosmetic Act and related regulations and guidance documents issued by FDA.