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AtCor MEDICAL

510(k) Summary – SphygmoCor CvMS

Date Prepared	5th March 2008
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APR 23 2008

Classification(s)

Product Code	Classification Reference	Common/Usual Name
DSK	21 C.F.R. § 870.1110 (Class II)	computer, blood-pressure
DRT	21 C.F.R. § 870.2300 (Class II)	monitor, cardiac (incl. cardio-tachometer & rate alarm)

Proprietary Name: **SphygmoCor® Cardiovascular Management System (CvMS)**

Predicate Device(s): **Primary** (un-modified device) - K070795 SphygmoCor Cardiovascular Management System CvMS (AtCor Medical Pty Ltd)

Secondary - K013434 Vascular Profiling System VP-2000 (Colin Corp)

Reason for submission: Modification to existing product

Intended Use

The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises.

The CvMS Pulse Wave Velocity (PWV) option is intended for use in obtaining PWV measurements. The PWV option is used on adult patients only.

Device Description

The SphygmoCor CvMS device (un-modified device) is a computerized tool for providing a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over the radial artery to capture a pressure waveform which is used to derive central pressure and is calibrated with a standard blood pressure cuff measurement. The CvMS is intended for use on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. In addition, the CvMS incorporates an option to enable users to measure Heart Rate Variability (HRV) in response to controlled exercises.

The SphygmoCor CvMS with the PWV option (modified device) is a software addition to the SphygmoCor CvMS device (K070795). This software feature provides an additional central arterial indice – Pulse Wave Velocity (PWV).

Description of Modification

The PWV option provides a modular software addition to the SphygmoCor CvMS (K070795). This simple software addition allows Pulse Wave Velocity to be calculated between two sites in the arterial tree (typically carotid-femoral). This is achieved by capturing arterial pressure waveforms (using tonometry) simultaneously with ECG data. The tonometry and ECG capabilities are unchanged from the predicate device.

The PWV software then calculates the time difference (Δt) between the two pressure waveforms using the ECG as a timing reference. The PWV is then simply calculated by measuring the distance between the two arteries and then dividing by Δt.

Device Comparison to Predicate(s)

A device comparison is provided in the table below which shows the differences between the Predicate devices and the modified device. In summary, the modified device has the following similarities to the previously cleared predicate devices:

- Similar intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

Comparison Table

	AtCor Medical SphygmoCor CvMS (Primary Predicate – Un-modified Device K070795)	Colin Corporation Vascular Profiling System VP-2000 (including pulse wave unit TU-100) (Secondary Predicate K013434)	AtCor Medical SphygmoCor CvMS (Modified Device)	Equivalence
Intended Use	The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises.	VP-2000/1000 is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases. It has a capability of measuring; non-invasive blood pressures, heart rate, pulse wave, and heart sound. It also has a capability of calculating ABI (Ankle Brachial Index), Pulse Wave Velocity and Augmentation Index. The instrument is used in a vascular laboratory, clinic, hospital, doctor's office, .and other medical facilities where the non-invasive peripheral vascular test is conducted. It is used on adult patients only.	The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises. The CvMS Pulse Wave Velocity (PWV) option is intended for use in obtaining PWV measurements. The PWV option is used on adult patients only.	Equivalent; The scope of this comparison is regarding the PWV function only.
Hardware	Common single Hardware (EM3) platform using Physiological Sensors: - Applanation Tonometry pressure sensor - ECG	Modular Hardware component for use in an existing system. Physiological Sensors: - Applanation Tonometry pressure sensors - BP Ankle & Brachial Cuff - ECG	Common single Hardware (EM3) platform using Physiological Sensors: - Applanation Tonometry pressure sensor - ECG	Equivalent; Primary – Same hardware Secondary – Same technology
Software	Modular Software component for use in an existing system.	Modular Software component for use in an existing system.	Modular Software component for use in an existing system.	Equivalent
Materials	Non-invasive physiological Sensors for PWA & HRV function: Tonometer: Tecason™ & RTV Silicon ECG: ECG cables and leads (FDA Cleared K945034) ECG Electrodes (FDA Cleared K946273)	Non-invasive physiological Sensors for PWV function: Pressure Sensor: RTV Silicon	Existing Non-invasive physiological Sensors for PWV function: Tonometer: Tecason™ & RTV Silicon ECG: ECG cables and leads (FDA Cleared K945034) ECG Electrodes (FDA Cleared K946273)	Equivalent;

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Performance				
PWV Calculation	Not Applicable	PWV is calculated by measuring the distance between distal and proximal sites then dividing by the pulse transit time (PTT) between the same sites.	PWV is calculated by measuring the distance between distal and proximal sites then dividing by the Mean DeltaT time (ΔT) between the same sites.	Equivalent to Secondary
Distance Measurement	Not Applicable	Performed manually by clinician.	Performed manually by clinician.	Equivalent to Secondary
Time Measurement	Not Applicable	Single recording using two pulse waveform measurements with the cuff-based Arterial Applanation Tonometer.	Two recordings in sequence are made at the distal and proximal sites using Applanation tonometry in conjunction with the ECG. The ECG serves as a reference to determine the Mean DeltaT time (ΔT) between the two sites.	Equivalent to . Secondary

Summary Comparison to Predicate Devices

Testing Summary

Design and Verification activities were performed on the SphygmoCor CvMS as a result of the risk analysis and product requirements in accordance with 21 CFR 820.30.

These tests included:

- Software verification
- Software validation (System Verification)

All test confirmed the product met the acceptance criteria.

Furthermore, a clinical comparison study was conducted which compared SphygmoCor CvMS side-by-side with the predicate. The tests results demonstrated similar performance between the two devices.

Conclusion

AtCor Medical has determined that the PWV software addition has not altered the safety and effectiveness of the device based on the company's design control procedures and test results from V&V and clinical comparison testing. The SphygmoCor CvMS system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Atcor Medical
c/o Mr. John Abram
Manager, Regulatory Affairs & Quality Assurance
11/1059-1063 Victoria Road
West Ryde NSW
Australia, 2114

Re: K080670
Modification to Sphygmocor Cardiovascular Management System
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II (two)
Product Code: DSK, DRT
Dated: April 01, 2008
Received: April 04, 2008

Dear Mr. Abram:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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AtCor MEDICAL

Indication for Use

510(k) Number (if known): _____

Device Name: SPHYGMOCOR CVMS-PWV

Indication for Use

The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

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Prescription Use ____X____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 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)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K080670