K102378

NOV - 2 2011

510K Summary

as required per 807.92(c)

510(k) Notification

VectraCor's VectraplexECG System with VectraplexAMI

1. **Submitters Name, Address:**

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Official Correspondent: Brad Schreck, President

Contact Person for this Submission: Brad Schreck

Date submission was prepared: August 11, 2011

2. **Trade Name, Common Name and Classification Name:**

a. Trade Name:

VectraplexECG System with VectraplexAMI

Product Code: V100V100

b. Common Name, Classification Name, Regulation Number

ECG	DPS	Class II	21 CFR 870.2340
ST Segment Monitor & Alarm	MLD	Class II	21 CFR 870.1025
ECG Interpretive Software	LOS		

3. **Predicate Device Identification:**
   - Micromedical – 12 lead simultaneous Cable – 510K K990266.
   - Primary Care Physicain Platform LLC, dba QRS Diagnostic, LLC. Cardioview / Office Medic - 510K # K083749 – This is the interpretive software- received 510K clearance ~Feb/Mar 2009. Previous 510k cleared was K974352 (Cardioview ECG Interpretative Software)
   - Philips EASI ECG Algorithm - 510K K033513

4. **Device Description**

The VectraplexECG System will be able to display and print a 12 lead ECG with 10 electrodes attached. In Addition, VectraplexECG will be able to derive up to a 15 lead ECG from only three measured leads (5 electrodes) and monitor the ECG changes that may be consistent with 12 lead ECG signs of acute myocardial infarction, via a displayed index number, VectraplexAMI.

5. **Indications for use :**

- VectraCor's VectraplexECG System with VectraplexAMI analyzes data from 3 leads (5 electrodes) and produces visual and audible alarms for ECG changes that may be consistent with 12-lead ECG signs of acute myocardial infarction. The device does not provide a diagnosis of acute myocardial infarction, but prompts the user to acquire a standard 12 lead ECG (using 10 electrodes) for interpretation by a physician. Monitoring patients with VectraplexAMI is only indicated for patients presenting with chest pain or other presumed anginal equivalents.
- The VectraplexECG System is intended to derive, display and print a derived 12 lead ECG as well as the X, Y, Z leads from the acquisition of just 3 leads (5 electrodes). The System also has the capability to acquire the standard 12 lead ECG using the standard 10 electrodes. The interpretation software is only available for the standard 12 lead ECG utilizing the standard 10 electrodes.
- VectraplexECG is intended to be used by healthcare professionals, i.e. Physicians, Nurses, Technicians, and Physician Assistants, where 12 lead and X, Y, Z leads are indicated for Hospitals and/or Clinics.
- The 12 lead interpretive software is a windows-based program intended to interpret electrocardiograms. The software receives, displays and stores a single, three or standard 12 lead simultaneous ECG recording, which is transmitted either locally or transtelephonically from an ECG monitor using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze and interpret the 12 lead ECG signal only.
- Device is for Adult use.

6. **Comparison to Predicate Device:**

The VectraplexECG System with VectraplexAMI is similar to Predicate devices:

- Same intended use as a 12 lead ECG monitor.
- Philips allows for derived ECG to be obtained by the use of 5 electrodes as does VectraplexECG.
- Philips, QRS Diagnostic and VectraCor calculate ST segments/ECG changes
- Are available in the same configurations
- Have the similar safety features
- Are made from the similar components and materials
- Use Identical electrodes
- All Three companies derive leads III, aVR, aVL, aVF
- Indications for use similarities
    - Philips EASI ECG Algorithm-(K033513 is incorporated into several Philips systems)
        - Derive a 12 lead ECG from 5 electrodes
        - Monitor ST segment changes of Adult patients
    - QRS Diagnostic
        - Office Medic Interpretive software is a windows-based program to interpret electrocardiograms. Office Medic receives, displays and stores a single or standard 12 lead Simultaneous ECG recording, which is transmitted either locally or transtelephonically from a monitor using proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal.
        - The 12 lead Simultaneous Cable acquires a patient's ECG via 10 leads connected to a patient's chest, converts the ECG signal into digital format, and transfers this information to a monitor or software system using a proprietary digital transfer protocol. K990266
        - The proposed device is intended to be used to acquire a patient's ECG signal and transmit it to a monitor or to a PC for display. K990266

7. Testing and Conclusions:

Verification, validation and testing procedures were performed to assure that the new device works and is substantially equivalent to the predicates. Testing supported the proposed label. VectraplexECG system with VectraplexAMI is designed to meet the design specifications and was validated using ECG databases.

The derived 15 lead ECG graphs were compared to measured ECG graphs to determine whether they are substantially equivalent with no difference in clinical outcome.

VectraCor has determined, based on the performance testing, that the VectraplexECG System with VectraplexAMI conforms to the design specifications and is substantially equivalent to the predicate devices for acquiring ECG leads and for monitoring a patient for ECG changes that may be

consistent with 12 lead ECG signs of acute myocardial infarction. The device, as designed, is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

NOV - 2 2011

Vectracor, Inc.
c/o Mr. Brad S. Schreck
President and CEO
35 Battle Ridge Trail
Totowa, NJ 07512

Re: K102378
Trade Name: Vectraplexecg system with vectraplexami
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS, MLD, LOS
Dated: September 7, 2011
Received: October 19, 2011

Dear Mr. Schreck:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4. Indications for use Statement:

510(k) Number (if Known): K102378

Device Name: VectraplexECG system with VectraplexAMI

Indications for Use:

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- Device is for Adult use.

Prescription Use ___YES___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___NO___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102378

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