



August 28, 2018

VectraCor, Inc.
Andrew Schreck
Manager of Regulatory Affairs
785 Totowa Rd. Suite 100
Totowa, New Jersey 07512

Re: K173952
Trade/Device Name: Universal SmartECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, MLD
Dated: July 26, 2018
Received: July 27, 2018

Dear Andrew 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Arielle Drummond -S

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)

K173952

Device Name

Universal SmartECG

Indications for Use (Describe)

- The 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 and convert the ECG signal into a digital format.
- 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.
- In 5 electrode mode, the System 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 Ischemic Injury (AMII), including Acute Myocardial Infarction (AMI). This mode is not intended to be a sole means of diagnosis, but prompts the user to acquire a standard 12 lead ECG (using 10 electrodes) for interpretation by a physician when the Cardiac Electrical Biomarker (CEB®) is 95 or greater. Monitoring patients with a CEB® is only indicated for patients presenting with chest pain or other presumed anginal equivalents.
- The interpretation software is only available for the standard 12 lead ECG utilizing the standard 10 electrodes.
- The System is intended to be used by healthcare professionals, or trained personnel where ECG monitoring /acquisition is indicated for hospitals and/or clinics.
- The System can be used within electro-surgical environments.
- Device is for Adult use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510k Summary



1. Submitters Name and Address:

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Official Correspondent: Andrew Schreck, Manager or Regulatory Affairs

Contact Person for this Submission: Andrew Schreck

Date submission was prepared: November 30, 2017

2. Trade Name, Common Name and Classification Name:

- a. Trade Name: Universal SmartECG
- b. Product Code: Z-7000-0500
- c. Common Name: Electrocardiogram, ECG, EKG
- d. Classification Name and Product Code:

| | | | |
|----------------------------|-----|----------|-----------------|
| ECG | DPS | Class II | 21 CFR 870.2340 |
| ST Segment Monitor & Alarm | MLD | Class II | 21 CFR 870.1025 |

3. Predicate Device Identification:

- o VectraplexECG System with VectraplexAMI (K102378)
- o Universal ECG (K990266)

4. Device Description:

The Universal SmartECG is a device with 10 lead wires attaching to electrodes on a patient's chest and one wire connecting to a computer. The system is able to display, store, and print a 12 lead ECG with 10 electrodes attached to the patient. In addition, The Universal SmartECG incorporates the VectraplexECG software (K102378), to derive up to a 15 lead (standard 12 leads and Frank vector X, Y, and Z leads) ECG from only three measured leads (5 electrodes). The device also monitors, in real-time, ECG changes that may be indicative of acute myocardial ischemic injury, including AMI*, via a displayed index number, the Cardiac Electrical Biomarker (CEB; VectraplexAMI). The system also provides the vector loops. The System's derivation algorithm is able to provide additional information based on geometric principals relating to the placement of electrodes on the body. The Cardiac Electrical Biomarker (CEB) is produced

based on an algorithm accounting for the multipolar contributions of the electrical field around the heart, which was FDA cleared via K102378.

*There will be times when the ECG shows signs consistent with AMI and the CEB shows signs consistent with AMI, but Troponin may not be completed or available at that time.

5. Indications for use:

- The 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 and convert the ECG signal into a digital format.
- 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.
- In 5 electrode mode, the System 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 Ischemic Injury, including Acute Myocardial Infarction. This mode is not intended to be a sole means of diagnosis, but prompts the user to acquire a standard 12 lead ECG (using 10 electrodes) for interpretation by a physician when the Cardiac Electrical Biomarker (CEB[®]) is 95 or greater. Monitoring patients with a CEB[®] is only indicated for patients presenting with chest pain or other presumed anginal equivalents.
- The interpretation software is only available for the standard 12 lead ECG utilizing the standard 10 electrodes.
- The System is intended to be used by healthcare professionals, or trained personnel where ECG monitoring /acquisition is indicated for hospitals and/or clinics.
- The System can be used within electro-surgical environments.
- Device is for Adult use.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

6. Comparison to Predicate Device:

The new Universal SmartECG System is the same principle device as the previous version of hardware, the Universal ECG (K990266). The databases for the VectraplexECG and Office Medic software modules, which are currently FDA-cleared, have been combined in this product. The technological characteristics (design, material, chemical composition, energy source) of the device are the same as the predicate.

The software, Office Medic and VectraplexECG, have been updated to be compatible with a new version of hardware, the Universal SmartECG (previously the Universal ECG). VectraCor has periodically released minor updates for the VectraplexECG System over the past few years.

The new Universal SmartECG System is the same principle device as the previous version of hardware, the Universal ECG (K990266). New hardware is designed to be compliant with IEC 60601-2-25:2011 standard. The Universal SmartECG system includes the hardware and 2 ECG software modules, VectraplexECG (K102378) and Office Medic. The Office Medic module has 2 components including ECG and spirometry functions. This 510k submission only affects the ECG component of Office Medic. The ECG component of Office Medic was previously known as CardioView 3000 (K083749) and was incorporated by Office Medic. The VectraplexECG and ECG component of Office Medic, which are FDA cleared and are currently 2 separate software programs, will share a database in the Universal SmartECG release. The technological characteristics (design, material, chemical composition, energy source) of the device are the same as the predicate.

Prior to this 510k submission, VectraCor has periodically released minor updates for the VectraplexECG System over the past few years. All updates have been considered in relation to the FDA memorandum "Deciding When to Submit a 510(k) for a Change to an Existing Device" and were determined that at the time a 510(k) was not necessary. These updates as well as enhancements to the new system include:

| Note to file enhancements | |
|---|---|
| <ul style="list-style-type: none"> Operating System upgrades (compatibility with new Windows versions) | <ul style="list-style-type: none"> Added reports to increase physician productivity with use of the VectraplexECG System |
| <ul style="list-style-type: none"> SQL Database upgrades | <ul style="list-style-type: none"> Added drivers and updates for better compatibility to the hardware device |
| <ul style="list-style-type: none"> Added a graph of the CEB over time | |

| Changes necessitated new 510k submission | |
|--|---|
| <ul style="list-style-type: none"> Updated software for compatibility to new data acquisition hardware (new revision of the previous hardware) | <ul style="list-style-type: none"> The 2 ECG modules, VectraplexECG and Office Medic, will share a database in the new release |
| <ul style="list-style-type: none"> Due to changes in the new hardware (Universal SmartECG) the device can now be used in electrosurgical environments | <ul style="list-style-type: none"> Updated the ECGlib.dll which measures ECG waveform components |
| <ul style="list-style-type: none"> An outer silicone strip has been added to the outside seams of the case | |

7. Testing and Conclusions:

Verification, validation and testing procedures were performed to assure that the new device works and is substantially equivalent to the predicate. Testing supported the proposed label.

The new hardware device, the Universal SmartECG, has been tested to, and passed, 60601-1,-1-2, and 2-25 standards.

Since this update is not changing the CEB algorithm or the derivation algorithm from the VectraplexECG System it has been determined that no clinical data is necessary to support these functions.

VectraCor has determined, based on the performance testing, that the Universal SmartECG conforms to the design specifications and is substantially equivalent to the predicate devices, Universal ECG and VectraplexECG, for acquiring ECG leads and for monitoring a patient for ECG changes that may be consistent with 12 lead ECG signs of myocardial ischemic injury, including AMI. The device, as designed, is substantially equivalent to the predicate devices.