DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 16, 2015

Vios Medical, Inc.
Megan Graham
Quality And Regulatory Advisor
7300 Hudson Blvd N, Ste 140
St. Paul, Minnesota 55128

Re: K150992
Trade/Device Name: Vios Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, DRG, FLL
Dated: November 16, 2015
Received: November 17, 2015

Dear Megan Graham:

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.

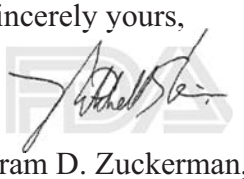
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150992

Device Name
Vios Monitoring System

Indications for Use *(Describe)*
The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological and vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of ECG, heart rate, pulse rate, functional oxygen saturation of arterial hemoglobin, and axillary temperature. VMS allows for the input of non-invasive blood pressure and can display data from peripheral devices. VMS can generate alerts when rate-based cardiac arrhythmias are detected and when physiological vital signs fall outside of selected parameters.

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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7. 510(k) Summary

Submitter:

Vios Medical, Inc.
7300 Hudson Rd Blvd N
Suite 140
St. Paul, MN 55128

Contact Person:

Megan Graham
Quality and Regulatory Advisor
megan@viosmedical.com
Office: 651-764-8467
Fax: 651-237-7003

Date Prepared: April 28, 2015

Trade Name: Vios Monitoring System™

Common Name: Vitals signs monitor

Regulation Classification:

- 21 CFR 870.2300 Cardiac Monitor including Cardiotachometer & Rate Alarm (Class II, Cardiovascular)
- 21 CFR 890.2910 Transmitters And Receivers, Physiological Signal, Radiofrequency (Class II, Cardiovascular)
- 21 CFR 880.2910 Clinical Electronic Thermometer (Class II exempt, General Hospital)

Review Panel: Cardiovascular

Product Codes: DRT, DRG, FLL

Predicate Devices:

- ViSi Mobile Monitoring System (K143751) for vitals monitoring and temperature
- VitalConnect Platform (K141167) for physiological data transmission and receipt

Device Description:

The Vios Monitoring System includes the following components:

- Bedside Monitor Software (BSM SW): Medical device software that analyzes and/or displays vitals data received via standard communication protocols from one or more compatible sensors or peripheral devices. The software runs on standard commercial IT equipment and can operate in stand-alone mode or networked mode using standard networking protocols. In networked mode, it can share its display with one or more redundant Vios proprietary viewers.

- Chest Sensor: Medical device sensor that allows short-term, continuous collection of physiological and vital signs data from patients, when attached to a Vios Chest Electrode. The Chest Sensor collects ECG, impedance, accelerometer, and axillary

temperature data. It allows patients to manually initiate a call alert to the BSM SW.

The Vios Monitoring System is compatible with the Vios Monitoring Platform.

Indications for Use:

The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological and vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of ECG, heart rate, pulse rate, functional oxygen saturation of arterial hemoglobin, and axillary temperature. VMS allows for the input of non-invasive blood pressure and can display data from peripheral devices. VMS can generate alerts when rate-based cardiac arrhythmias are detected and when physiological vital signs fall outside of selected parameters.

Summary of Substantial Equivalence:

The Vios Monitoring System is substantially equivalent to the predicate devices with respect to vitals signs monitoring in a healthcare facility (product codes DRT, DRG, and FLL). Both the VMS and its predicates are wireless vitals monitoring systems that can operate in stand-alone or networked mode. Additional functionality of the predicate devices is outside the scope of the Vios Monitoring System.

The safety and effectiveness of the Vios Monitoring System design have been confirmed through non-clinical testing and conformance to vital signs monitoring, electrical safety (60601), electromagnetic compatibility (60601), usability (62366), risk management (14971), software development lifecycle (62304), and biocompatibility standards (10993).

Non-Clinical Testing:

The following bench testing was conducted to demonstrate safety and efficacy of the Vios Monitoring System:

- Design Verification and Validation
- Standards Compliance Testing (60601-1, 60601-1-2, 60601-1-8, 60601-2-27, and 60601-2-49)
- Usability Testing (Formative and Summative)
- Reliability and Performance Testing
- Transportation Simulation Testing

Conclusion:

Vios Medical considers the Vios Monitoring System to be safe, effective, and substantially equivalent to the legally marketed predicate devices.