June 22, 2018

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

Re: K172586
Trade/Device Name: Vios Monitoring System™ Model 2050
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, DQA, DPZ, DRG
Dated: May 22, 2018
Received: May 23, 2018

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172586

Device Name
Vios Monitoring System™ Model 2050

Indications for Use *(Describe)*
The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of 7-lead ECG, heart rate, respiratory rate, pulse rate, functional oxygen saturation of arterial hemoglobin, non-invasive blood pressure, and patient posture and activity. VMS allows for the input of body temperature, 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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510(k) Summary

Submitter:	Vios Medical, Inc. 700 Commerce Dr. Suite 190 Woodbury, MN 55125
Contact Person:	Megan Graham Director, Quality and Compliance megan@viosmedical.com Office: 651-764-8467 Fax: 651-237-7003
Date Prepared:	June 22, 2018
Trade Name:	Vios Monitoring System™ Model 2050
Common Name:	Vitals signs monitor
Primary Regulation:	21 CFR 870.2300 Cardiac Monitor including Cardiotachometer & Rate Alarm
Other Regulation:	21 CFR 890.2910 Transmitters And Receivers, Physiological Signal, Radiofrequency 21 CFR 870.2710 Ear oximeter 21 CFR 870.2700 Oximeter
Classification:	Class II
Review Panels:	Cardiovascular, Anesthesiology
Product Codes:	Primary: DRT Other: DQA, DPZ, DRG
Predicate Devices:	VMS Model 1000 (reference K150992) VisiMobile Monitoring System (reference K152341) Nonin Pulse Ox Model 6100C (reference K092101).
Device Description:	The Vios Monitoring System (VMS) Model 2050 is a wireless mobile medical device platform that allows caregivers in healthcare settings to monitor patient vitals. VMS includes Vios-proprietary monitoring software and a Vios-proprietary vitals sensor with two Vios-proprietary adapters. It is compatible with a medical grade, Bluetooth™-enabled NIBP cuff. The VMS BSM SW Model B2050 is stand-alone software that can receive, analyze, and display physiological vitals data from one or more patient-worn sensors via standard communication protocols (Bluetooth™). It runs on a commercial IT platform and is intended to be used in conjunction with the Vios Chest Sensor and Vios Lead Adapters and can support peripheral, medical grade, Bluetooth™-enabled devices.

	The VMS Chest Sensor Model CS2050 is a small, patient-worn, non-sterile, multiple use, and rechargeable sensor that acquires 3-channel ECG, bioimpedance, 2-channel pulse oximetry, and tri-axial accelerometer data. The sensor contains signal acquisition firmware (embedded software) and wirelessly communicates acquired data via standard communication protocols (Bluetooth™) to the BSM SW for analysis and display. The Chest Sensor has a button that, when pressed, sends a patient call alert to the BSM SW. VMS Chest Sensor Adapter Models L2050E (Pulse Ox Ear Adapter) and L2050F (Pulse Ox Finger Adapter) are plastic, non-sterile, patient-worn, multiple use pulse oxygenation sensors that connect to the Vios Chest Sensor and are secured to the patient via medical grade ECG electrodes.
Indications for Use:	The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of 7-lead ECG, heart rate, respiratory rate, pulse rate, functional oxygen saturation of arterial hemoglobin, non-invasive blood pressure, and patient posture and activity. VMS allows for the input of body temperature, 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 Technology Comparison	The Vios Monitoring System Model 2050 technology is based on the Vios Monitoring System Model 1000 and shares a common architecture and run on a commercial IT platform. The VMS Model 2050 Chest Sensor uses a standard medical grade ECG electrode and an adapter plate to collect additional ECG, impedance, accelerometer, and pulse oximetry data (finger or ear). The VMS Model 2050 BSM SW has been updated to generate and display 7-lead ECG data, respiratory rate, SpO2, pulse rate, posture, activity, and non-latched physiological alarms. It can also display non-invasive blood pressure data from a medical grade, Bluetooth™-enabled NIBP cuff.
Summary of Non-Clinical, Clinical, and Conformance Testing	The safety, effectiveness, and substantial equivalency of the VMS Model 2050 have been confirmed through the following non-clinical, clinical, and conformance testing: • Electrical safety, EMC, and vitals sign monitoring standards (IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-2-27, IEC 60601-2-49, EC53) • Biocompatibility standards (ISO 10993) • Usability and human factors standards (EN 62366) • Transportation Simulation testing (ASTM D4169-16) • Software development life cycle (EN 62304) • Risk Management (ISO 14971) • Pulse oximetry clinical testing (IEC 80601-2-61) • Respiratory Rate clinical testing
Conclusion:	Vios Medical's evaluation of the substantial equivalence of the Vitals Monitoring System Model 2050 to the predicate devices was based on a comparison of device classification, intended use, indications for use and

	contraindications, warnings, technical characteristics, and performance characteristics. Vios Medical also performed conformance testing and clinical testing to demonstrate substantial equivalency. Based on this comparison, Vios Medical concludes that Vios Monitoring System Model 2050 is substantially equivalent to the predicate devise and does not introduce new safety or effectiveness issues.