March 22, 2024

Murata Vios, Inc.
John Lansdown
General Manager, Quality, Regulatory, & Compliance
700 Commerce Drive, #190
Woodbury, Minnesota 55125

Re: K232354
Trade/Device Name: Vios Monitoring System (Vios Monitoring System(TM) Model 2050; Vios Central Station Monitor/Vios Central Server Software 2050)
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: QYW, DQA, DPZ, DRG, DXJ, OUG
Dated: February 22, 2024
Received: February 22, 2024

Dear John Lansdown:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232354

Device Name
Vios Monitoring System(TM) 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 the physiological vital signs fall outside of selected parameters.

VMS can also generate alerts when cardiac arrhythmias (Tachycardia, Bradycardia, Asystole, Ventricular Tachycardia/ Ventricular Fibrillation and Atrial Fibrillation/ Atrial Flutter) are detected.

The ECG rhythm analysis is intended for use by medically qualified professionals in the identification of arrhythmia events and to aid in clinical review of arrhythmias and medical interventions.

The Vios CSM/CS Software is indicated for use by healthcare professionals for the purpose of centralized monitoring of patient data within a healthcare facility. The Vios CSM/CS SW receives, stores, manages, and displays patient physiological and waveform data and alarms generated by Vios proprietary patient vitals monitoring software.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Summary

Submitter:	Murata Vios, Inc. 700 Commerce Drive, Suite 190 Woodbury, MN 55125
Contact Person:	John Lansdown General Manager, Quality, Regulatory, & Compliance john.lansdown@murata.com Office: 651-888-8125
Date Prepared:	8/4/2023
Trade Names:	Vios Monitoring System™ Model 2050 Vios Central Station Monitor/Central Server Software 2050
Common Name:	Vital Signs monitor
Regulation:	21 CFR § 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm). 21 CFR § 870.2300 Cardiac Monitor (including cardiotachometer and rate alarm) 21 CFR § 870.2910 Radiofrequency physiological signal transmitter and receiver 21 CFR § 870.2700 Oximeter 21 CFR § 870.2710 Ear oximeter 21 CFR § 870.2450 Medical cathode-ray tube display 21 CFR § 880.6310 Medical device data system
Classification:	Class II
Review Panels:	Cardiovascular, Anesthesiology
Product Codes:	QYW, DQA, DPZ, DRG, DXJ, OUG
Predicate Devices:	Vios Monitoring System™ Model 2050 (K172586) Vios Central Station Monitor/Central Server Software 2050 (K173107) ViSi Mobile Monitoring System (K180472)
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. The VMS includes a proprietary monitoring software, Chest Sensor, Finger Adapter and Central Server and Central Monitoring Station. 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 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 the physiological vital signs fall outside of selected parameters. VMS can also generate alerts when cardiac arrhythmias (Tachycardia, Bradycardia, Asystole, Ventricular Tachycardia/ Ventricular Fibrillation and Atrial Fibrillation/ Atrial Flutter) are detected. The ECG rhythm analysis is intended for use by medically qualified professionals in the identification of arrhythmia events and to aid in clinical review of arrhythmias and medical interventions. The Vios CSM/CS Software is indicated for use by healthcare professionals for the purpose of centralized monitoring of patient data within a healthcare facility. The Vios CSM/CS SW receives, stores, manages, and displays patient physiological and waveform data and alarms generated by Vios proprietary patient vitals monitoring software.
Summary of Substantial Equivalence	The Vios Monitoring System has the following similarities and differences with the indicated predicate devices: Intended use –The proposed device, Vios Monitoring System monitors the same vital signs as the predicate, previously cleared Vios Monitoring System (K172586) except for the addition of arrhythmia detection feature, which is included in the predicate, Visi Monitoring System (K180472). Considered together, the intended use of the proposed device is the same as the Vios Monitoring System the addition of arrhythmia detection like the Visi System. The Vios Monitoring System, is similar to the predicate devices, is intended to be used by licensed practitioners in a healthcare environment. Device Performance –The modified Vios Monitoring System with the addition of arrhythmia detection has been verified to meet the performance requirements as outlined in the consensus standard ANSI/AAMI EC57:2012 - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms. The subject device's performance was also evaluated using additional records from LTAF, AAEL and VFDB database. The predicate device (K180472) has also been tested for compliance to ANSI/ AAMI EC57 for the arrhythmia features. Technology –The Vios Monitoring System is unchanged from its predicate submission (K172586) except for the addition of arrhythmia detection measurement. The VMS arrhythmia detection measurement feature are based on similar characteristic features to that of the ViSi System predicate device (K180472) for displaying alarms for VT/VF and AF. Safety –The Vios Monitoring System with the addition of arrhythmia detection measurement has been verified to meet the requirements of the recognized consensus standards, which is the same as that of the predicate device.

Summary of Non-Clinical, Clinical, and Conformance Testing	The non-clinical tests for evaluation of performance of Vios system with the addition of arrhythmia alarms is based on ANSI/AAMI EC57, showing substantial equivalence to the predicate (K180472). The subject device's performance was also evaluated using additional records from LTAF, AAEL, and VFDB database, other than referred in the standard. Other system performance remains unchanged from the predicate (K172586) except the following standard: • AAMI/ANSI EC57 The safety and effectiveness of the VMS Model 2050 based on the following standards remains unchanged: • 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) • Transportation Simulation testing (ASTM D4169-16) • Software development life cycle (EN 62304) • Usability and human factors standards (EN 62366) • Risk Management (ISO 14971) • Pulse oximetry clinical testing (ISO 80601-2-61) • Respiratory Rate clinical testing • Standard for evaluation of Wireless Coexistence (ANSI C63.27)
Conclusions:	Based on the results from the non-clinical tests performed, Murata Vios considers the Vios Monitoring System to be as safe, as effective and substantially equivalent to the legally marketed predicate devices.