January 23, 2025

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

Re: K241728
Trade/Device Name: Vios Monitoring System(TM) Model 2050;
Vios Central Station Monitor/Vios Central Server Software 2050
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DRT, DQA, DPZ, DRG, DXJ, OUG
Dated: June 14, 2024
Received: June 14, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen C. Browning -S

LCDR Stephen Browning
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

k241728

Device Name

Vios Monitoring System(TM) Model 2050 (2050);
Vios Central Station Monitor/Vios Central Server Software 2050 (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 (NIBP) continuously, and patient posture and activity. VMS allows for the input of non-invasive blood pressure and 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.

The non-invasive Blood Pressure Tracking feature is based on Pulse Arrival Time (PAT), which is obtained utilizing ECG and PPG signals following a calibration process using an FDA-cleared oscillometric blood pressure monitor. This feature is not intended for use in critical care environment.

The Vios Central Station Monitor (CSM) and Central Server (CS) Software (SW) is indicated for use by healthcare professionals for the purpose of centralized monitoring of patient data within a healthcare facility. The Vios CSM SW and 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.

510(k) Summary

Submitter:	Murata Vios, Inc. 700 Commerce Drive, Suite 190 Woodbury, MN 55125
Contact Person:	John Lansdown Director, Quality, Regulatory, & Compliance john.lansdown@murata.com Mobile: 972-984-0977
Date Prepared:	July 1, 2024
Trade Names:	Vios Monitoring System™ Model 2050 Vios Central Station Monitor/Central Server Software 2050
Common Name:	Vital Signs monitor
Regulation:	21 CFR § 870.1130 Noninvasive blood pressure measurement system 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:	DXN, DRT, DQA, DPZ, DRG, DXJ, OUG
Predicate Devices:	Primary Predicate: ViSi Mobile Monitoring System (K130709) Secondary Predicates: Vios Monitoring System™ Model 2050 (K172586) Vios Central Station Monitor/Central Server Software 2050 (K173107)
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 (NIBP) continuously, and patient posture and activity. VMS allows for the input of non-invasive blood pressure and 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. The non-invasive Blood Pressure Tracking feature is based on Pulse Arrival Time (PAT), which is obtained utilizing ECG and PPG signals following a calibration process using an FDA-cleared oscillometric blood pressure monitor. This feature is not intended for use in critical care environment. The Vios Central Station Monitor (CSM) and Central Server (CS) Software (SW) is indicated for use by healthcare professionals for the purpose of centralized monitoring of patient data within a healthcare facility. The Vios CSM SW and 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 subject device has been updated with software modifications (addition of algorithm for blood pressure tracking and supporting UI modifications) which has similar technological characteristics as that of primary predicate, K130709. The features other than blood pressure tracking and the physical components remain unchanged from the secondary predicates (K172586 and K173107). Vios Central Station Monitor/Central Server essentially remains the same apart from UI modifications to support blood pressure tracking. • Basic Principle: The subject device tracks blood pressure via PAT (Pulse Arrival Time) using the time delay between ECG measured from the chest and the pulsatile PPG waveform measured at the base of finger/thumb using the pulse oximeter of the subject device. The sensors unit for ECG and PPG remains the same as K172586 and for the blood pressure tracking, the same underlying principle is used by the primary predicate, Visi Mobile Monitoring System, K130709. • Calibration (initialization): For tracking the blood pressure based on PAT, it requires coefficients from an input blood pressure for calibration. This characteristic is the same as the Visi Mobile Monitoring System (K130709). The predicate and the subject device are calibrated to a specific oscillometric cuff device. Both the subject and predicate devices can only be calibrated when the PAT is stable, and the calibration is achieved by pairing PAT during cuff inflation with the BP readings of the calibration device during the same cuff inflation period. Thus, the method of calibration remains the same between the subject device and the predicate. • Device Performance: The clinical study was performed across a range of subjects, representative of the intended population, to validate this measured change. The results demonstrate the performance meeting the all consensus standards requirement and are substantially equivalent to the predicate device. The subject device has been verified and clinically validated to meet the requirements of the recognized consensus standards. The results demonstrate that essential technological characteristics between the subject device and the predicate devices are the same, and do not raise new questions about safety or effectiveness, and testing establishes equivalent performance as compared to predicate devices.

Summary of Non-Clinical, Clinical, and Conformance Testing	The bench (non-clinical) testing for the addition of blood pressure tracking feature to the VMS Model 2050 is done using system validation testing and compliance testing for applicable clauses according to IEC 80601-2-30. The clinical testing and analysis is performed according to applicable clauses from ISO 81060-2, IEEE 1708, and ISO 81060-3 for validation using reference invasive blood pressure measurement on the radial artery. The results were within the acceptance criteria, similar to the predicate device. The other system performance remains unchanged from the predicate (K172586) and show conformance to: • 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 and clinical tests, Murata Vios considers the Vios Monitoring System to be as safe, as effective and substantially equivalent to the legally marketed predicate devices.