July 26, 2018

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

Re: K173107
Trade/Device Name: Vios Central Station Monitor/Vios Central Server Software 2050
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: September 28, 2017
Received: September 29, 2017

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,

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

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)*
K173107

Device Name
Vios Central Station Monitor/Central Server Software Model 2050

Indications for Use *(Describe)*
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

Submitter: Vios Medical, Inc.
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Contact Person: Megan Graham
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Date Prepared: September 28, 2017

Trade Name: Vios Central Station Monitor/Central Server Software Model 2050

Common Name: Central monitoring software

Regulation: 21 CFR Part 870.2450 Medical cathode-ray tube display

Classification: Class II

Review Panels: Cardiovascular

Product Codes: DXJ

Predicate Device: GE Healthcare CARESCAPE Central Station v2 (reference K162012)

Device Description: The Vios CS SW enables the Vios Monitoring System to be used in networked mode within a healthcare IT network and runs on commercial IT equipment.

The Vios CS SW operates as a communications hub that can pass the data generated by Vios proprietary vitals monitoring software to one or more remote viewing software applications, without modifying the data.

The Vios CSM SW is the remote viewing software of the Model 2050 system. It allows up to 16 devices to be displayed on one screen and runs on a commercial IT device that satisfies defined Vios-defined technical specifications.

Indications for Use: 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 CSM/CS SW Model 2050 is substantially equivalent to the predicate device with respect to central station monitoring in a healthcare facility (product code DXJ). Both the Vios CSM/CS SW Model 2050 and its predicates meet the same standards of safety and efficacy. Risk analysis of Vios CSM/CS SW Model 2050 demonstrates that no additional risks are introduced. Additional functionality of the predicates is outside the scope of the Vios CSM/CS SW Model 2050.

Non-Clinical Testing:

The performance of the Vios CSM/CS SW Model 2050 has been evaluated through non-clinical testing and analysis:

- System and Subsystem Software Development Life Cycle (62304)
- System and Subsystem Design Verification and Validation Testing
- System and Subsystem Risk Management (14971)

Conclusion:

Vios Medical considers the Vios CSM/CS Software Model 2050 to substantially equivalent to the legally marketed predicate device.