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

May 24, 2017

Global Instrumentation, LLC
Jason DeMaso
Quality Assurance Manager
8104 Cazenovia Road
Manlius, New York 13104

Re: K162463
Trade/Device Name: Matrix Data Management System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 21, 2017
Received: April 24, 2017

Dear Jason DeMaso:

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,

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

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K162463

Device Name
Matrix Data Management System

Indications for Use *(Describe)*
The Matrix Data Management System software and associated accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiological signals, as identified below, for the purpose of assisting the clinician in the diagnosis and monitoring of various disease and/or treatment regimens. The Matrix Data Management System software also provides non-diagnostic functions such as patient management, data security, search tools for patient and/or test records and support for exporting data to Electronic Medical Record systems.

The Matrix Data Management System and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients, subject to any specific contraindications identified below.

--Ambulatory Blood Pressure Monitor Indication For Use--
The Oscar 2, system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.
Optionally, Oscar 2 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff.
It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects).

--Matrix Holter System Indication For Use--
The M12 Matrix Holter System is intended to be used as a Holter ambulatory electrocardiograph system for the purpose of screening for ECG rhythm disturbances over periods up to 48-hours. The Matrix Holter System is intended for use under the supervision of a Physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia. This procedure is commonly called a Holter procedure which captures ECG rhythm abnormalities which may be infrequent or provoked by activities outside of the physician office.
The M12 Matrix Holter System is comprised of the Matrix Holter Recorder (MI2R) and the Matrix Holter System Application (Ml2A).
The Matrix Holter Recorder component of the system will be worn by the patient and is used to record ambulatory electrocardiograph data from the patient. The Matrix Holter System Application is used to analyze the data recorded by the Matrix Holter Recorder.

The subject Devices will provide the following diagnostic functions:
* Acquiring, viewing, storing and printing ambulatory ECG waveforms from patients using the Matrix Holter Recorder and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
* Using optional Holter algorithms to generate measurements, data presentations and graphical presentations on an advisory basis for patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.
* Using optional interpretive algorithms to generate measurements, data presentations, graphical presentations, and

interpretive statements on an advisory basis for patients of sixteen (16) years of age and above. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.

---Matrix Mini ECG Monitor Indication for Use--
The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare facilities. The system is indicated for use in pediatric and adult patients.

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

[As described in 21 CFR 807.92]

Owner's Name: Global Instrumentation LLC.

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Manlius, NY 13104 USA

Contact Person: Jason DeMaso
Quality Assurance Manager
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Date Prepared: August, 15th 2016

Trade Name: Matrix Data Management System

Common Name: Matrix Data Management System

Classification Name: Class II, Noninvasive blood pressure measurement system (21 CFR 870.1130, Product Code – DXN).

Predicate Devices: CardioPerfect Workstation
Welch Allyn, Inc.
510(k) Number K052158

NOTE: The Matrix Data Management System is substantially equivalent in intended use and technology, as well as operation and performance, to Welch Allyn CardioPerfect Workstation (K052158) for is functionality in Ambulatory ECG Monitoring, Patient Monitoring and Ambulatory Blood Pressure Monitoring.

Description of the Device:

The Matrix Data Management System is intended for use by clinicians for managing sensor data of pediatric and adult patients in health care facilities.

The Matrix Data Management System (DMS) provides functionality to manage data acquired from various physiologic data acquisition sensors. The DMS supports a mechanism to initialize sensors, acquire data from the sensors and provide summaries of the results obtained from the sensors.

The current sensors supported by the Matrix Data Management System include Ambulatory blood pressure monitoring with optional sensors for Ambulatory ECG and Patient Monitoring.

The Ambulatory blood pressure monitoring sensor used within DMS is approved as Oscar 2 (K151520).

The Ambulatory ECG Monitoring sensor used within the DMS is approved as Matrix Holter System, Model M12 (K051730).

The Patient Monitoring sensor used within the DMS is approved as Matrix Mini ECG Monitor (K152701)

(Refer to VOL_014; 002_Device Description for further information)

Indications For Use:

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The Matrix Data Management System and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients, subject to any specific contraindications identified below.

Ambulatory Blood Pressure Monitor Indication For Use

The Oscar 2 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses. Optionally, Oscar 2 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff.

It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects).

Matrix Holter System Indication For Use

The M12 Matrix Holter System is intended to be used as a Holter ambulatory electrocardiograph system for the purpose of screening for ECG rhythm disturbances over periods up to 48-hours. The Matrix Holter System is intended for use under the supervision of a Physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia. This procedure is commonly called a Holter procedure which captures ECG rhythm abnormalities which may be infrequent or provoked by activities outside of the physician office.

The M12 Matrix Holter System is comprised of the Matrix Holter Recorder (MI2R) and the Matrix Holter System Application (Ml2A).

The Matrix Holter Recorder component of the system will be worn by the patient and is used to record ambulatory electrocardiograph data from the patient. The Matrix Holter System Application is used to analyze the data recorded by the Matrix Holter Recorder.

The subject Devices will provide the following diagnostic functions:

- Acquiring, viewing, storing and printing ambulatory ECG waveforms from patients using the Matrix Holter Recorder and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional Holter algorithms to generate measurements, data presentations and graphical presentations on an advisory basis for patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.
- Using optional interpretive algorithms to generate measurements, data presentations, graphical presentations, and interpretive statements on an advisory basis for patients of sixteen (16) years of age and above. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.

Matrix Mini ECG Monitor Indication for Use

The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare facilities. The system is indicated for use in pediatric and adult patients.

Technological Characteristics:

The Matrix Data Management System (DMS) provides functionality to manage data acquired from various physiologic data acquisition sensors. The DMS supports a mechanism to initialize sensors, acquire data from the sensors and provide summaries of the results obtained from the sensors. The predicate device selected is the CardioPerfect Workstation (CPWS) which provides similar functionality. The DMS and CPWS both provide support for multiple types of sensors and both provide support for Ambulatory Blood Pressure Monitoring sensors (ABPM) which has a product code of DXN. The current sensors supported by the Matrix Data

Management System include Ambulatory blood pressure monitoring with optional sensors for Ambulatory ECG and Patient Monitoring.

The Ambulatory blood pressure monitoring sensor used within DMS is approved as Oscar 2 (K151520).

The Ambulatory ECG Monitoring sensor used within the DMS is approved as Matrix Holter System, Model M12 (K051730).

The Patient Monitoring sensor used within the DMS is approved as Matrix Mini ECG Monitor (K152701)

The device was tested in accordance with AAMI/IEC 60601-1 Electrical Safety 60601-1 Ed. 3.1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The device passed all applicable test requirements and confirmed that the device is substantially equivalent to the predicate device.

There is no device performance based on animal testing required for this device or the predicate device.

No clinical studies were utilized for the purpose of obtaining safety and/or efficacy data for this device or the predicate device.

(Refer to VOL_013; 002_Executive Summary for further information)

Non-Clinical Tests:

Verification and validations were conducted to ensure expected performance of the Matrix Data Management System. *(Refer to VOL_022_Test Results)*

The Matrix Data Management System was tested to evaluate its safety and effectiveness based on the following standards:

- ISO 14971: 2007 - Medical devices - Application of risk management to medical devices
- IEC 62304: 2006 - Medical device software - Software life cycle processes
- IEC 60601-1 3rd Edition - Medical Design Standards

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

Conclusion:

Based on the information presented in this 510(k) premarket notification, the Global Instrumentation LLC Matrix Data Management System is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed device cited in this submission.