DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 12, 2017

GE Healthcare
Robert Casarsa
Regulatory Affairs Leader
8200 West Tower Ave.
Milwaukee, Wisconsin 53223

Re: K170199
Trade/Device Name: Unity Network ID v8
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: April 13, 2017
Received: April 14, 2017

Dear Robert Casarsa:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K170199

Device Name

Unity Network ID v8

Indications for Use *(Describe)*

The Unity Network ID is indicated for use in data collection and clinical information management through networks with independent bedside devices. The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

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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510k Summary

I. SUBMITTER

GE Healthcare
GE Medical Systems Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Contact Person: Robert Casarsa
Phone: 414-362-3062
Date Prepared: April 7, 2017

II. DEVICE

Name of Device: Unity Network ID v8
Common or Usual Name: Physiological Patient Monitor
Classification Name: 21 CFR 870.2300 Monitor, Physiological, Patient (without arrhythmia detection or alarms
Regulatory Class: II
Product Code: MWI

III. PREDICATE DEVICE

Unity Network ID v7 K142840
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Unity Network ID system communicates patient data from sources other than GE Medical Systems Information Technologies, Inc. equipment to a clinical information system, central station, and/or GE Medical Systems Information Technologies Inc. patient monitors.

The Unity Network ID acquires digital data from eight serial ports, converts the data to Unity Network protocols, and transmits the data over the monitoring network to a Unity Network device such as a patient monitor, clinical information system or central station.

Accessories include device specific interface cables and mounting hardware.

V. INDICATONS FOR USE

The Unity Network ID is indicated for use in data collection and clinical information management through networks with independent bedside devices. The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

The indication for use is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Technological Characteristics of the Unity Network ID are exactly the same as all previous versions of the Unity Network ID.

The device collects data from equipment connected to any of eight RS-232 serial communications ports. The data is converted from the independent bedside manufacturer's RS-232 protocol into the GEMS IT Unity Network protocol. Data collected consists of real-time waveforms, parameter numeric data, device configuration data and parameter alarm data.

The communication between the Unity Network ID and an interfaced device is bi-directional. However, communication to an interfaced device is limited to information requests or to transfer of patient demographic data. No commands are sent which could affect how the interfaced device operates.

The device operates in either a stand-alone mode or a peripheral mode of operation.

Hardware:

1) No change to the Unity Network ID hardware
2) Create interface cables for the newly supported devices
3) Create new interface cable for existing device:
    a) Draeger Fabius GS (K011404)

Software:

This version of Unity Network ID adds support for the following devices:

(a) Capnostream 20p Monitor (K123690)
(b) SenTec Digital Monitor (K151329)
(c) Hamilton G5 Ventilator (K131774)
(d) Vista BIS (K072286)
(e) Edwards EV1000 (K160552)
(f) Draeger Perseus A500 (K133886)

(g) Draeger Babylog VN500 (K093632)
(h) Draeger Savina 300 (K121886)
(i) Draeger Evita V300 (Not for sale in US)
(j) Draeger Oxylog 3000 Plus (K103625)
(k) Puritan Bennett 980 Ventilator (K131252)

The following categories of devices are supported by the Unity Network ID:

- Anesthesia Machines
- Continuous Cardiac Output Monitors
- Gas Analyzers
- Infusion Pumps
- Patient Monitors
- Pulse Oximeters
- Transcutaneous Monitors
- Urometers
- Ventilators
- Blood Analyzer
- Bispectral Index Monitor

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
No biocompatibility testing was performed as the Unity Network ID has no patient contact.

Electrical safety and electromagnetic compatibility (EMC)

The Unity Network ID was designed and tested for compliance with the following standards:

1. IEC 60601-1:2005, +Corr 1:2006, +Corr 2:2007 +A1:2012 - Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
2. IEC 60601-1-2:2007 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 60601-1-6:2010 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
4. IEC 62336: 2007 + A1:2014 - Medical devices -- Part 1: Application of usability engineering to medical devices

Software Verification and Validation Testing
Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, where a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information of through the action of a care provider.

The following bench tests were performed:

- Unit Testing: Code reviews and/or static code analysis are the methods are adopted for the software unit verification to ensure the unit acceptance criteria, as defined in the SDLC procedure, are met.
- Integration Testing: Functional procedures were executed to test the interface requirements.
- Regression Testing: Regression testing was performed to ensure additional confidence of the build or to test the regression of the software build.

Mechanical and acoustic testing
No mechanical or acoustic testing was performed on the Unity Network ID as the only changes were software based.

Animal Study
No animal studies have been performed on the Unity Network ID.

Clinical Studies
No clinical studies have been performed on the Unity Network ID.

VIII. CONCLUSIONS

This version of the Unity Network ID (v8) is substantially equivalent to the prior versions (v1-v8). The submitted device uses the same technology for the interface, has no device hardware changes, and adds new interface cables for the newly interfaced devices. Verification testing has assured that the design outputs meets the requirements of the design inputs. Testing to internationally recognized standards demonstrate the safety of the device.