December 6, 2018

GE Healthcare
Brandon O'Shea
Senior Regulatory Affairs Leader
8200 West Tower Ave.
Milwaukee, Wisconsin 53223

Re: K183116
Trade/Device Name: Unity Network ID
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: November 8, 2018
Received: November 9, 2018

Dear Brandon O'Shea:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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,

Stephen C. Browning -S5

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)*
K183116

Device Name
Unity Network ID

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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510(k) Summary

In accordance with 21 CFR 807.92 the following summary information is provided:

Date:	8 November 2018
Submitter:	GE Healthcare 8200 W. Tower Ave. Milwaukee, WI 53223
Primary Contact Person:	Brandon O'Shea Regulatory Affairs Leader GE Medical Systems Information Technologies, Inc. Email: brandon.oshea@ge.com Ph: (414) 323-3147
Secondary Contact Person:	Monica Morrison Senior Regulatory Affairs Director GE Medical Systems Information Technologies, Inc. Ph: (608) 515-3077
Device Trade Name:	Unity Network ID
Common/Usual Name:	Physiological Patient Monitor
Classification Names: Product Code:	21 CFR 870.2300 Monitor, Physiological, Patient (without arrhythmia detection or alarms) MWI
Predicate Device(s):	Unity Network ID V8 (K170199)
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.

Intended 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.
Technology:	The device converts the output from independent bedside device's RS-232 protocol into the Unity Network protocol.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Unity Network ID V9 and its applications were tested to, and comply with, applicable voluntary standards. The Unity Network ID V9 was tested to assure that the device meets its design specifications. Testing included all new or modified features. The following quality assurance measures were applied to the development and testing of the of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, Unity Network ID V9, did not require clinical studies to support substantial equivalence.

Comparison:	Hardware: 1) No change to the Unity Network ID hardware 2) Update encoding of cables to detect newly supported devices (no change to physical cable) Software: Add interface support for the following third-party devices: a) Edwards HemoSphere (K163381) b) GE Aisys CS2 (K170872) c) GE Giraffe Incubator (K101788) d) GE Giraffe Omnibed Incubator (K101788) e) GE Giraffe Warmer (K070377) f) GE Panda Warmer (K070377) g) Maquet Flow-i (K160665) h) Maquet Servo-air (Not for sale in US) i) Maquet Servo-n (K151814) j) Maquet Servo-s (K123149) k) Maquet Servo-U (K151814) l) Nellcor PM1000N (K141518)
Conclusion:	GE Healthcare considers the Unity Network ID V9 to be as safe, as effective, and its performance is substantially equivalent to the predicate device(s).