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

September 15, 2016

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

Re: K162012
Trade/Device Name: CARESCAPE Central Station V2
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: July 20, 2016
Received: July 21, 2016

Dear Mr. 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 yours,

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)*
K162012

Device Name
CARESCAPE Central Station v2 (CSCS)

Indications for Use *(Describe)*
The CARESCAPE Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data within a hospital or clinical environment.

The CARESCAPE Central Station is intended to collect, display and print information from a network, including patient demographics, physiological parameters and waveforms, alarm annunciation and/or other non-medical information from monitors and telemetry systems. Physiological parameters and waveforms include electrocardiograph (ECG), pulse oximetry (SPO2), invasive blood pressures (IBP), non-invasive blood pressure (NIBP), respiration (RR), ventilator (VNT), carbon dioxide (CO2), oxygen (O2), mass spectrometry (Gas), temperature (Temp) and bispectral index (BIS). Beat to beat patient information for parameters and waveforms from the bedside and telemetry systems can be displayed. Patient monitor and telemetry system settings can be adjusted. Parameter values derived from patient data can be calculated, displayed, and printed.

The CARESCAPE Central Station supports the ability to access information from GE products and hospital intranet in a web browser format. Additionally, CARESCAPE Central Station supports the ability to access patient information collected from the CARESCAPE network and stored on a network server.

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 of information is provided:

Date: July 20, 2016

Submitter: GE Medical Systems *Information Technologies,* Inc.
8200 West Tower Avenue
Milwaukee, WI 53223

Contact Person: Robert Casarsa
Regulatory Affairs Leader
GE Medical Systems *Information Technologies,* Inc.
Email: robert.casarsa@ge.com
Ph: (414) 362-3063
Cell: (262) 358-1082

Device Trade Name: CARESCAPE Central Station v2 (CSCS)

Common/Usual Name: Central Station

Classification: 21 CFR 870.2450

Product Code: DXJ

Secondary Codes:
BZQ 21 CFR 868.2375 monitor, breathing frequency
CBR 21 CFR 868.1700 analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CBS 21 CFR 868.1620 analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBQ 21 CFR 868.1500 analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
CCK 21 CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-phase

CCL 21 CFR 868.1720 analyzer, gas, oxygen, gaseous-phase
DXN 21 CFR 870.1130 system, measurement, blood-pressure, noninvasive
DOA 21 CFR 870.2700 oximeter
DPT 21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)
DSB 21 CFR 870.2770 plethysmograph, impedance
DSK 21 CFR 870.1110 computer, blood-pressure
GWQ 21 CFR 882.1400 full-montage standard electroencephalograph
FLL 21 CFR 880.2910 thermometer, electronic, clinical
NHO 21 CFR 868.1500 analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)
NHP 21 CFR 868.1500 analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)
NHQ 21 CFR 868.1500 analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)
BSE 21 CFR 868.1640 Helium gas analyzer
JEG 21 CFR 868.1075 Argon gas analyzer
CCI 21 CFR 868.1690 Nitrogen gas analyzer

Predicate Device(s): CARESCAPE Central Station (K133882)
MUSE ST Guard (K842308)
12SL V22 – ACS (K092369)
MUSE CV (K110132)

Device Description: The CARESCAPE Central Station (CSCS) is based on a PC technology platform and is user friendly for easy operation using a simple logical screen menu. The interactive controls include the use of a computer mouse, keyboard and touch screen. Optional writers for the purpose of graphing waveforms and printing patient information include a 2-inch Direct Digital Writer and/or a laser printer. Internal speakers provide alarm audio indication.

The CSCS provides centralized monitoring of patients connected to GE Medical Systems *Information Technologies*, Inc.'s monitors and telemetry transmitters. It may be configured to display up to four real-time waveforms per patient for up to 16 patients and up to 9 waveforms for a single selected patient. Waveforms include ECG, SPO2, respiration ventilation flow and pressure, invasive blood pressure and CO2.

The device acts as a (1) viewing station, (2) reviewing station and (3) live monitoring station by obtaining its information from acquisition devices off the CARESCAPE network.

Patients may be admitted to and discharged from monitors and telemetry devices from the central location. The central station is also the control and display device for telemetry monitoring.

The CSCS provides secondary annunciation of alarms from primary bedside monitoring devices and primary annunciation of alarms from wireless telemetry devices.

The display window for each patient shows waveforms and vital information including: patient name, bed number, arrhythmia and alarm visual indicators, system messages, audio pause indicator, audio alarm indicator, alarm message line, heart rate, PVC count, transmitter number, ECG lead label, pacemaker status, ST measurement, and graph status. Physiological parameter values and waveforms from the GE Medical Systems *Information Technologies,* Inc.s' monitors can be displayed and printed from the CSCS.

Non-real time patient information available for reviewing and printing includes: Graphic Trends, Tabular Numeric Vital SignsTrends, Event HistoryReview, Full Disclosure, Calipers, and ST Review. Data can be printed to a networked laser printer. In the case of Event Review, data can also be printed to a PDF file.

The CARESCAPE Central Station also provides remote control of patient monitor and telemetry device configuration settings that includes:

- Admitted patient demographics like name and medical record number;
- Alarm Settings like high/low limit values and alarm priority levels;
- Printing settings like selection of which waveforms to print on graphs and the printed output destinations;
- ECG settings like primary lead selection, ST analysis on/off and pace maker detection on/off;
- Initiate and terminate combination monitoring where a bedside patient monitor accepts ECG data from a telemetry transmitter;
- Non-ECG parameter settings like respiration lead selection

and NBP cuff size selection.
The Full Disclosure option provides up to 144 hours of beat-to-beat patient information from the bedside or telemetry system for parameters and waveforms. Full Disclosure also stores resting ECGs from 16 patients once per minute for 144 hours and up to 2000 alarm histories with waveform snippets for each patient. This information can be displayed at the CSCS in detailed and summary mode formats.

Intended Use: The CARESCAPE Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data within a hospital or clinical environment.

The CARESCAPE Central Station is intended to collect, display and print information from a network, including patient demographics, physiological parameters and waveforms, alarm annunciation and/or other non-medical information from monitors and telemetry systems. Physiological parameters and waveforms include electrocardiograph (ECG), pulse oximetry (SPO2), invasive blood pressures (IBP), non-invasive blood pressure (NIBP), respiration (RR), ventilator (VNT), carbon dioxide (CO2), oxygen (O2), mass spectrometry (Gas), temperature (Temp) and bispectral index (BIS). Beat to beat patient information for parameters and waveforms from the bedside and telemetry systems can be displayed. Patient monitor and telemetry system settings can be adjusted. Parameter values derived from patient data can be calculated, displayed, and printed.

The CARESCAPE Central Station supports the ability to access information from GE products and hospital intranet in a web browser format. Additionally, CARESCAPE Central Station supports the ability to access patient information collected from the CARESCAPE network and stored on a network server.

Technology: The CARESCAPE Central Station employs the same functional scientific technology as its predicate devices. The device is a software driven device running on a PC platform. The

CARESCAPE Central Station V2 utilizes new hardware platforms and embedded operating system.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The CARESCAPE Central Station and its applications were tested to, and comply with, applicable voluntary standards. The CARESCAPE Central Station 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, CARESCAPE Central Station, did not require clinical studies to support substantial equivalence.

Comparison: The following contains the differences of the CARESCAPE Central Station V2 when compared to the predicate CARESCAPE Central Station V1:

Hardware

- Upgraded Platform; faster processor, increased RAM, increased SSD Flash Media, removed external RS-232 Serial port, removed DVI and VGA interfaces, removed unused network port, and increased MC support to 1000Mbps.

2 configurations available, Desktop and Integrated hardware options
Supports widescreen displays
Eliminated cooling fan for low power CPU

Software

Upgraded platform from XP based OS to Windows 7 based.

Historical Trending

Added ability for additional trends where the bedside is already monitoring the now supported additional parameters

Alarming

Settings are password protected
Alarm levels now conform to IEC 60601-2-27:2011 Clause 208.6.6.2.105, Clause 208.6.1.2, and Clause 208.6.11.2.2

Printing

- Compatible with PCL 6 Compatible HP Universal Printers to support additional printers.

Conclusion: GE Healthcare considers the CARESCAPE Central Station to be as safe and as effective, and its performance substantially equivalent to the predicate devices.