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

GE Medical Systems, LLC
% Ms. Elizabeth Mathew
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

March 24, 2015

Re: K150193
Trade/Device Name: Customer Remote Console (CRC)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 28, 2015
Received: January 30, 2015

Dear Ms. Mathew:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K150193

Device Name
Customer Remote Console (CRC)

Indications for Use *(Describe)*

The Customer Remote Console Software Option allows remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating GE Healthcare medical imaging devices. This access must be granted by the technologist operating the system. The remote access is only available for systems supporting GE remote connectivity capability. Images reviewed remotely are not for diagnostic use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary

Customer Remote Console (CRC)

Traditional 510(k)

510(k) Summary

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

Date:	March 20 , 2015
Submitter:	GE Healthcare (GE Medical Systems, LLC) Establishment Registration Number - 2126677 3000 N Grandview Blvd., Waukesha, WI – 53188
Primary Contact Person:	Elizabeth Mathew Regulatory Affairs Manager GE Healthcare 9900 Innovation Drive, Wauwatosa, WI – 53226 Mail Stop: RP-2124 Phone: (262) 521-6658 Email: Elizabeth.Mathew@ge.com
Secondary Contact Person:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: 262-424-9547 Email: John.Jaeckle@ge.com
Device: Trade Name:	Customer Remote Console
Common/Usual Name:	CRC
Classification Names:	21 CFR 892.2050 Picture archiving and communication system
Product Code:	90 LLZ
Predicate Device:	MAGNETOM Systems with syngo Expert-i option (K052423) SYNGO EXPERT-I (K061449) AW Server (K081985)

Device Description:	Customer Remote Console (CRC) is a customer facing software application that is fully contained within a hospital provider network. It provides remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating the GE Healthcare medical imaging devices in the context of training, procedure assessment, and scanning parameter management. Remote users will be able to log into a GEHC imaging medical device from a device (Laptop/Desktop) which meets minimum required specifications anywhere within the provider network. This allows users to spread imaging knowledge and expertise without limitation of time or distance. This access must be granted by the technologist operating the system and it can also be revoked at any time by the technologist. While a remote session is taking place, the technologist operating the system will have complete control of the session at all times. Also, each remote session will be controlled via a secure credential that is managed by the technologist operating the system. Connections to a medical device are limited to one remote session at a time to maintain strict control over who is remotely interacting with the system. Images reviewed remotely are not for diagnostic use.
Intended Use:	Customer Remote Console Software Option provides remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating the scanner. This guidance includes training, procedure assessment, and scanning parameter management.
Indication for Use:	The Customer Remote Console Software Option allows remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating GE Healthcare medical imaging devices. This access must be granted by the technologist operating the system. The remote access is only available for systems supporting GE remote connectivity capability. Images reviewed remotely are not for diagnostic use.
Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:	The proposed device, Customer Remote Console (CRC) employs the same fundamental scientific technology as its predicate devices: MAGNETOM Systems with syngo Expert-i option (K052423), SYNGO EXPERT-I (K061449), AW Server (K081985).

The Customer Remote Console (CRC) is a software solution that allows remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating the GE Healthcare medical imaging devices. Access to imaging devices is controlled through the CRC Server, which controls the connections between imaging devices and CRC Clients. CRC is intended to allow remote users to support technologists for training purposes or for assistance with acquiring images which is the same principle as the MAGNETOM Systems with syngo Expert-i option (K052423) and SYNGO EXPERT-I (K061449). CRC clients can be either inside the customer's local area network (LAN) or outside their LAN, connected to their virtual private network (VPN). The predicates, MAGNETOM Systems with syngo Expert-i option (K052423) and SYNGO EXPERT-I (K061449), also allow remote access to a customer workplace from a PC in the same local area network (LAN). CRC User has to be authenticated before the user can connect to the imaging device. The predicate devices, MAGNETOM Systems with syngo Expert-i option (K052423), SYNGO EXPERT-I (K061449) and AW Server (K081985) also require User Authentication. MAGNETOM Systems with syngo Expert-i option (K052423), SYNGO EXPERT-I (K061449) and the proposed device CRC provides the capability for the customer to select the display quality during a remote session. CRC allows only one remote session with an imaging medical device at a given time which is the same principle as the MAGNETOM Systems with syngo Expert-i option (K052423) and SYNGO EXPERT-I (K061449). In the predicate devices (MAGNETOM Systems with syngo Expert-i option (K052423), SYNGO EXPERT-I (K061449)) and proposed device CRC, a remote user does not have access to certain icons on the console of the imaging medical device. In both the predicate devices (MAGNETOM Systems with syngo Expert-i option (K052423) , SYNGO EXPERT-I (K061449)) and proposed device CRC, the technologist operating the scanner and the remote users both have the capability to terminate the remote session.

Potential Adverse Effects on Health:

Potential hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications and user requirements.
- Adherence to software development lifecycle procedures (SDLC)
- Instruction for Use provided for the safe and effective use by users.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The following quality assurance measures were applied to the development of CRC:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance/Safety testing (Verification)
- Clinical Scenarios testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, CRC, does not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers CRC to be as safe, as effective, and substantially equivalent to the predicate devices.