GE Healthcare
% Allena Holzworth
Regulatory Affairs Leader
500 W. Monroe Street
Chicago, Illinois 60661

October 27, 2023

Re: K232346
Trade/Device Name: Digital Expert Access with Remote Scanning
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LLZ
Dated: August 4, 2023
Received: August 4, 2023

Dear Allena Holzworth:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Daniel Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K232346

Device Name

Digital Expert Access with Remote Scanning

Indications for Use *(Describe)*

Digital Expert Access with Remote Scanning is a remote scan assistance solution which allows remote control of an MR Imaging Device including the ability to initiate a scan remotely. This access provides real time communication mechanisms between the remote and onsite users to facilitate the acquisition occurring on the device. Access must be granted by the onsite user operating the system. 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 510(k) Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.92:

**Date:** August 4, 2023

**Submitter:**
GE HealthCare
500 W. Monroe Street
Chicago, IL 60661

**Primary Contact:**
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**Subject Device Name:** Digital Expert Access with Remote Scanning
**Device Classification:** Class II
**Regulation Number:** 21 CFR 892.1000 Magnetic Resonance Diagnostic Device
21 CFR 892.2050 Medical image management and processing system
**Product Code:** LNH, LLZ

### Predicate Device Information

**Predicate Device 1**
**Device Name:** SIGNA Hero
**Manufacturer:** GE Medical Systems, LLC
**510(k) Number:** K213668
**Regulation Number:** 21 CFR 892.1000 Magnetic Resonance Diagnostic Device
**Product Code:** LNH

**Predicate Device 2**
**Device Name:** Customer Remote Console (CRC)
**Manufacturer:** GE Medical Systems, LLC
**510(k) Number:** K150193

| | |
|---|---|
| **Regulation Number:** | 21 CFR 892.2050 Medical image management and processing system |
| **Product Code:** | LLZ |

**Predicate Device 3**

| | |
|---|---|
| **Device Name:** | MAGNETOM Systems with syngo Expert-i option |
| **Manufacturer:** | Siemens Medical Solutions, INC. |
| **510(k) Number:** | K052423 |
| **Regulation Number:** | 21 CFR 892.1000 Magnetic Resonance Diagnostic Device |
| **Product Code:** | LNH |

**Device Description**

Digital Expert Access is a variation of the Customer Remote Console cleared under K150193. It is a remote scan assistance solution designed to address the skill variability in technologists and their need for on-demand support by allowing them to interact directly with a remote expert connected to the hospital network. By enabling the collaboration between an Onsite Technologist and Remote Expert, Digital Expert Access helps the onsite technologist to seek guidance and real time support on scanning related queries including but not limited to training, procedure assessment, and scanning parameter management.

Digital Expert Access with Remote Scanning introduces a feature that enables the Remote Expert to initiate a scan and make changes in real time during the scanning session. This remote scan feature is only available when Digital Expert Access is connected to a compatible GE HealthCare MRI system.

Digital Expert Access with Remote Scanning enables the following capabilities for the Onsite Technologist and the Remote Expert:

1. Collaborative session between an Onsite Technologist and Remote Expert
2. Real-time scanner screen share and live annotation
3. Remote console access and control
4. Remote Scan Initiation

Digital Expert Access with Remote Scanning is not intended for diagnostic use or patient safety-related management. This solution is not intended to be used by individuals who are not properly trained in the operation of GE HealthCare Medical Imaging systems. Digital Expert Access with Remote Scanning does not directly interface with any patients and requires the Onsite Technologist to be continuously present throughout the scanning procedure. Digital Expert Access with Remote Scanning does not acquire any MRI images, nor does it do any post image processing. All image acquisition and image processing is conducted by the GE HealthCare MRI system.

**Intended Use**

Digital Expert Access with Remote Scanning is intended as a remote collaboration tool to view and review MR images, to remotely control MR Imaging Devices and to initiate MRI scans remotely.

**Indications for Use**

Digital Expert Access with Remote Scanning is a remote scan assistance solution which allows remote control of an MR Imaging Device including the ability to initiate a scan remotely. This access provides real time communication mechanisms between the remote and onsite users to facilitate the acquisition occurring on the device. Access must be granted by the onsite user operating the system. Images reviewed remotely are not for diagnostic use.

**Technology**

The proposed device, Digital Expert Access with Remote Scanning, employs similar fundamental scientific technology as its predicate devices.

**Comparisons**

Digital Expert Access with Remote scanning is substantially equivalent to the predicate devices, SIGNA Hero (K213668), Customer Remote Console (CRC) (K150193) and MAGNETOM Systems with syngo Expert-i option (K052423). The proposed device is intended to be a remote scan assistance solution, allowing the onsite technologist to connect to a remote expert to view/review images, provide real time guidance and initiate an MRI scan remotely. The table below summarizes the substantive feature/technological similarities and differences between the predicate devices and the proposed device:

**Table 5-1: Comparison Table for Digital Expert Access with Remote Scanning and its Predicate Devices**

| Items | Predicate 1: SIGNA Hero (K213668) | Predicate 2: Customer Remote Console (CRC) K150193 | Predicate 3: MAGNETOM Systems with syngo Expert-i option (K052433) | Proposed: Digital Expert Access with Remote Scanning |
|---|---|---|---|---|
| User Interface Functions | PC-based | PC-based | PC-based | Tablet-based/PC-based |
| Operator Interface | Keyboard, mouse | Keyboard, mouse | Keyboard, mouse | Touch LCD, Keyboard, touchpad |
| Remote Viewer interactive control | N/A | User profile (preferences) is associated with an Administrator, User with View role, or User with Guidance role. | The Expert-I status dialog is used to determine if the remote user should have Full Access or View Only access to the syngo Workplace | The onsite user initiates a request through DEA which initiates an acceptance screen on the user interface. Once the request is acknowledged on the scanner, the onsite user must validate the connection by entering the session password for the remote session. |
| Imaging System Modality for Remote Scanning | N/A | N/A | MR | MR |
| Intended Users | Radiologist, Expert Technologist | Radiologist, Expert Technologist | Radiologist, Expert Technologist | Radiologist, Expert Technologist |

| | | | | |
|---|---|---|---|---|
| Scan Initiation | Scan initiated by onsite technologist | Scan initiated by onsite technologist | Remote user can initiate scan on MR scanners remotely | Remote user can initiate scan on MR scanners remotely |
| Patient/Scanner Support during Acquisition | Onsite technologist oversees patient support during scanning acquisition | N/A – CRC is not intended for scan acquisition | Onsite technologist oversees patient support during scanning acquisition | Onsite technologist oversees patient support during scanning acquisition |

**Clinical and Non-Clinical Tests**

Summary of Non-Clinical Tests

Digital Expert Access with Remote Scanning has successfully completed the design control testing per GE HealthCare's quality system. It was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. No new questions of safety and effectiveness and no unexpected test results were observed.

The following quality assurance measures have been applied to the development of the system:

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Safety Testing (Verification)
- Performance Testing (Verification, Validation)
- Software Release

Digital Expert Access with Remote Scanning verification was conducted to demonstrate proper implementation of its design requirements. The testing and results did not raise any new issues of safety and effectiveness.

In addition, verification and validation testing was conducted on the bench by integrating Digital Expert Access with Remote Scanning on a subset of GE HealthCare MRI systems to ensure a Remote Expert was able to perform remote scanning on GE HealthCare MRI systems.

Design verification and validation testing confirmed that the safety and effectiveness of the device has not been affected. The test plans and results have been executed with acceptable results.

Summary of Clinical Testing

The subject of this premarket submission, Digital Expert Access with Remote Scanning did not require clinical studies to support substantial equivalence to enable the remote scanning feature on GE HealthCare MRI systems.

**Substantial Equivalence Conclusion**

The introduction of Digital Expert Access with Remote Scanning does not result in any new potential safety risks and uses the same technology as the predicate devices, including the initiation of an MRI scan remotely. After analyzing design verification and validation testing on the bench it is the conclusion of GE

HealthCare that Digital Expert Access with Remote Scanning to be as safe, as effective, and performance is substantially equivalent to the predicate devices.