June 8, 2022

GE Medical Systems, LLC
% Glen Sabin
Regulatory Affairs Director
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K213717
Trade/Device Name: AIR Recon DL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: May 9, 2022
Received: May 10, 2022

Dear Glen Sabin:

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/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 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 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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of In Vitro Diagnostics
and 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)*
K213717

Device Name
AIR Recon DL

Indications for Use *(Describe)*

AIR Recon DL is a deep learning based reconstruction technique that is available for use on GE Healthcare 1.5T, 3.0T, and 7.0T MR systems. AIR Recon DL reduces noise and ringing (truncation artifacts) in MR images, which can be used to reduce scan time and improve image quality. AIR Recon DL is intended for use with all anatomies, and for patients of all ages. Depending on the anatomy of interest being imaged, contrast agents may be used.

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.

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510(k) Summary

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

Date: 6 June 2022

Submitter:
GE Medical Systems, LLC
3200 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact:
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Senior Regulatory Affairs Manager
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Device Trade Name: AIR Recon DL

Common / Usual Name: MR System

Classification Name: Magnetic Resonance Diagnostic Device
Regulation Number: 21 CFR 892.1000
Primary Product Code: LNH

Predicate Device:
510(k) Number: K193282
Device Name: SIGNA Premier
Manufacturer: GE Medical Systems, LLC

Reference Devices:
510(k) Number: K202238
Device Name: SIGNA Artist
Manufacturer: GE Medical Systems, LLC

510(k) Number: K211118
Device Name: SIGNA 7.0T
Manufacturer: GE Medical Systems, LLC

Device Description:

AIR Recon DL is a software feature intended for use with GE Healthcare MR systems. It is a deep learning based reconstruction technique that removes noise and ringing (truncation) artifacts from MR images. AIR Recon DL is an optional feature that is integrated into the MR system software and activated through a purchasable software option key.

This 510(k) submission has been triggered by a modification to AIR Recon DL to expand its compatible pulse sequences to include PROPELLER and 3D Cartesian acquisitions.

Indications for Use:

The Indications for Use statement for the proposed device is provided below:

> ***AIR™ Recon DL is a deep learning based reconstruction technique that is available for use on GE Healthcare 1.5T, 3.0T, and 7.0T MR systems. AIR Recon DL reduces noise and ringing (truncation artifacts) in MR images, which can be used to reduce scan time and improve image quality. AIR Recon DL is intended for use with all anatomies, and for patients of all ages. Depending on the anatomy of interest being imaged, contrast agents may be used.***

Comparison of Technological Characteristics:

The proposed AIR Recon DL software feature that is the subject of this 510(k) is similar to the feature of the same name included in the predicate SIGNA Premier, K193282. The predicate device used deep learning convolutional neural networks to remove noise and ringing from certain 2D Cartesian acquisitions. The proposed AIR Recon DL has been modified to be compatible with PROPELLER and selected 3D Cartesian acquisitions. Both the proposed AIR Recon DL and the predicate device use neural networks that have similar architecture, and were trained using similar methods and data.

The proposed AIR Recon DL is intended for use on GE Healthcare 1.5T, 3.0T, and 7.0T MR systems. The AIR Recon DL feature included in the predicate device was intended for use with only GE Healthcare 3.0T systems. However, the same algorithm described in the predicate device (K193282) is also cleared for use in GE Healthcare 1.5T systems (SIGNA Artist - K202238), and 7.0T systems (SIGNA 7.0T - K211118).

Summary of Nonclinical Testing:

AIR Recon DL has undergone phantom testing to evaluate the feature and its impact on image quality, including SNR, sharpness, and low contrast detectability. For PROPELLER acquisitions, analysis was also performed to compare Apparent

Diffusion Coefficient (ADC) maps calculated from images using AIR Recon DL to those calculated from conventional images.

The nonclinical testing demonstrated that AIR Recon DL does improve SNR and image sharpness while maintaining low contrast detectability. AIR Recon DL was also able to maintain image SNR and did not sacrifice sharpness for images acquired with a reduced scan time. ADC maps were not adversely impacted by the use of AIR Recon DL. The nonclinical testing passed the defined acceptance criteria and did not identify any adverse impacts to image quality or other concerns related to safety and performance.

Summary of Clinical Testing:

A reader evaluation study was performed on images acquired across a variety of pulse sequences and anatomies. The study involved 133 cases as summarized below:

Source of data:

- 129 patient cases from 10 different clinical sites
- 4 cases from healthy subjects obtained at a GE Healthcare facility

Equipment used:

- GE Healthcare 1.5T MR systems: 51 cases
- GE Healthcare 3.0T MR systems: 82 cases

Protocols used:

- 3D acquisitions: 92 cases
- PROPELLER acquisitions: 41 cases

Anatomical coverage:

- Body (breast, abdomen, and pelvis): 42 cases
- Cardiac: 10 cases
- Neuro (head, neck, and spine): 57 cases
- Musculoskeletal (shoulder, wrist, hip, knee, and ankle): 24 cases

Use of exogenous contrast:

- With Contrast: 31 cases
- Without Contrast: 102 cases

Presence of pathology:

- With pathology: 124 cases
- Without pathology: 9 cases

Readers were asked to compare the AIR Recon DL images to conventional images (without AIR Recon DL) reconstructed from the same acquired raw data. Each image pair was evaluated independently by three radiologists. The results confirmed that the AIR Recon DL feature provides images with equivalent or better image quality in terms of apparent signal to noise ratio (133 out of 133 cases), sharpness (133 out of 133 cases), and lesion conspicuity (123 out of 124 cases with pathology). The radiologists reading the images also indicated a preference for the AIR Recon DL images over conventional images in 99% of the evaluations.

Evaluations were also made of AIR Recon DL images from shorter scan time acquisitions and images without AIR Recon DL taken with longer scan times. Despite the shorter scan times, the AIR Recon DL images were rated as better or equivalent image quality for all 22 image pairs.

Sample images involving the presence of motion and other common artifacts were evaluated both with and without the AIR Recon DL feature. The sample images show that AIR Recon DL does not significantly change the appearance of motion artifacts.

Additionally, images were evaluated to confirm that the use of AIR Recon DL does not adversely affect the accuracy of quantitative measurements such as contrast pharmacokinetics, lesion sizes, and brain volumetry results. The analysis showed strong agreement between measurements made using conventional and AIR Recon DL images.

Conclusions Drawn from Performance Testing:

The nonclinical and clinical testing demonstrated that AIR Recon DL satisfies the product claims of improved SNR and image sharpness, and can enable shorter scan times while preserving SNR and image sharpness.

The proposed AIR Recon DL software feature has been developed under GE Healthcare's quality system and is at least as safe and effective as the earlier version of AIR Recon DL in the legally marketed predicate device. The performance testing did not identify any new hazards, adverse effects, safety concerns, or performance concerns that are significantly different from those associated with MR imaging in general.

Therefore, GE Healthcare believes that AIR Recon DL is substantially equivalent to the predicate device and is safe and effective for its intended use.