May 30, 2023

GE Medical Systems,LLC (GE Healthcare)
% Glen Sabin
Regulatory Affairs Director
3200 N Grandview Blvd.
WAUKESHA WI 53188

Re: K223523
Trade/Device Name: Sonic DL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: April 28, 2023
Received: April 28, 2023

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,

Daniel M. 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)*
K223523

Device Name
Sonic DL

Indications for Use *(Describe)*
Sonic DL is a Deep Learning based image reconstruction technique that is available for use on GE Healthcare 1.5T and 3.0T MR systems. Sonic DL reconstructs MR images from highly under-sampled data, and thereby enables highly accelerated acquisitions. Sonic DL is intended for cardiac imaging, and for patients of all ages.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date: 24 May 2023

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

Primary Contact: Glen Sabin
Regulatory Affairs Director
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Phone: 262 720-8872
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Device Trade Name: Sonic 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: K213668
Device Name: SIGNA Hero
Manufacturer: GE Medical Systems, LLC

Device Description:

Sonic DL is a new software feature intended for use with GE Healthcare MR systems. It consists of a deep learning based reconstruction algorithm that is applied to data from MR cardiac cine exams obtained using a highly accelerated acquisition technique.

Sonic DL is an optional feature that is integrated into the MR system software and activated through a purchasable software option key.

Indications for Use:

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

Sonic DL is a Deep Learning based image reconstruction technique that is available for use on GE Healthcare 1.5T and 3.0T MR systems. Sonic DL reconstructs MR images from highly under-sampled data, and thereby enables highly accelerated acquisitions. Sonic DL is intended for cardiac imaging, and for patients of all ages.

Comparison of Technological Characteristics:

The proposed Sonic DL software feature that is the subject of this 510(k) is similar to the 2D FIESTA Cine feature with ASSET acceleration that is included in the predicate SIGNA Hero, K213668. The predicate device uses breath holds and a conventional parallel imaging acceleration technique (ASSET) that typically achieves acceleration factors between 2 and 4, and acquires each slice in 6 to 10 heartbeats. Sonic DL can achieve acceleration factors as high as 12, and enables single heartbeat (1 R-R) imaging with either breath holds or free breathing.

Summary of Nonclinical Testing:

The performance of the Sonic DL reconstruction algorithm has been evaluated using simulated data generated from an MRXCAT phantom, and a digital phantom. Model accuracy metrics such as Peak-Signal-to-Noise (PSNR), Root-Mean-Square Error (RMSE), Structural Similarity Index Measure (SSIM), and Mean Absolute Error (MAE) were used to compare simulated Sonic DL images with different levels of acceleration and numbers of phases to the fully sampled images. Additionally, line profiles across the heart at different phases were used to evaluate both in-plane and temporal sharpness.

The nonclinical testing demonstrated that Sonic DL is capable of reconstructing Cine images from highly under sampled data that are similar to the fully sampled Cine images in terms of image quality and temporal sharpness.

Summary of Clinical Testing:

Two reader evaluation studies were performed using Sonic DL images acquired from clinical sites and from healthy volunteers at GE Healthcare facilities. In one study, three radiologists were asked to determine various quantitative measurements such as left ventricular volumes, ejection fraction, and cardiac output using both conventional Cine and Sonic DL image sets as summarized below:

Number of image series evaluated:	107
Number of unique subjects:	57
Patients:	46
Healthy volunteers:	11
Sites contributing data:	7
GE Healthcare facilities:	2
External collaborators (clinical sites):	5
Gender of subjects:	
Male:	35
Female:	22
Age range of subjects:	12 weeks to 82 years old

Pathology: Subjects from clinical sites included examples of various cardiac pathology, including structural heart disease, ischemic cardiomyopathy, and non-ischemic cardiomyopathy.

Equipment Used: GE HealthCare 1.5T and 3.0T MR Systems

Acquisition Parameters:	
Field of View:	28 – 46 cm
In-plane resolution:	1.3 – 2.2 mm (both x and y directions)
Acquired Temporal Resolution (frame rate)	23.7 – 70.2 ms

The results showed that the inter-method variability (coefficient of variability comparing functional measurements taken with Sonic DL images versus measurements using the conventional ASSET Cine images) was smaller than the inter-observer intra-method variability for the conventional ASSET Cine images for all parameters, indicating that Sonic DL is suitable for performing functional cardiac measurements.

In a second study, three radiologists were asked to perform blinded image quality assessments of both conventional 2D FIESTA Cine images with ASSET acceleration, and Sonic DL images obtained with different number of R-R intervals and different acceleration factors. This study involved 127 image sets which included a subset of the subjects described above, and included different cardiac views such as short axis, long axis, and aortic valve images. The results of this study showed that on average the Sonic DL images were rated as being of diagnostic quality while providing a significant reduction in scan time compared to the conventional ASSET Cine images.

In addition to the two reader studies described above, other tests were performed. Similar to the nonclinical testing using the digital phantom, model accuracy and temporal sharpness evaluations were conducted using in vivo cardiac cine images obtained from 19 health volunteers.

Finally, clinical testing has been performed to demonstrate that Sonic DL is capable of achieving a 12 times acceleration factor and obtaining free-breathing images in a single heartbeat (1 R-R). Functional measurements using Sonic DL 1 R-R free breathing images from 10 subjects were compared to functional measurements using the conventional ASSET Cine breath hold images, and showed close agreement. Additionally, the image quality of 13 Sonic DL 1 R-R free breathing cases was evaluated by a U.S. board certified radiologist, and scored higher than the corresponding conventional free breathing Cine images from the same subjects.

The results of the clinical testing confirmed that the Sonic DL feature provides images that are of diagnostic quality, and that allow functional measurements that are within typical inter reader variability to the same measurements taken with conventional images. Additionally, the Sonic DL feature provided significantly shorter scan times that the conventional Cine imaging.

Conclusions Drawn from Performance Testing:

The nonclinical and clinical testing demonstrated that Sonic DL satisfies the product claims of reducing scan times while preserving image quality, enabling single heartbeat functional imaging, and enabling rapid free-breathing functional imaging.

The proposed Sonic DL software feature has been developed under GE Healthcare's quality system and is at least as safe and effective as the 2D FIESTA Cine feature with ASSET acceleration that is used 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 cardiac cine MR imaging in general.

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