GE Medical Systems, LLC.
% Ms. Laura Turner
Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA WI 53188

February 13, 2019

Re: K183161
Trade/Device Name: SnapShot Freeze 2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: November 13, 2018
Received: November 15, 2018

Dear Ms. Turner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183161

Device Name
SnapShot Freeze 2

Indications for Use *(Describe)*
SnapShot Freeze 2 is designed for use with gated cardiac acquisitions to reduce cardiac induced motion artifacts.

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

SnapShot Freeze 2

510(k) SUMMARY OF SAFETY AND EFFECTIVNESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date:	2/4/2019
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Laura Turner Regulatory Affairs Leader Phone 262-548-4588 Email: laura.turner@ge.com
Secondary Contacts:	Helen Peng Regulatory Affairs Director GE Healthcare Tel: 262-424-8222 Email: hong.peng@meg.ge.com

PRODUCT IDENTIFICTION

Device Name:	SnapShot Freeze 2
Regulation number/ Product Code	21 CFR 892.1750 Computed tomography x-ray system / JAK
Secondary Regulation number/Product Code	21 CFR 892.2050 Picture archiving and communications system/ LLZ
Device Classification	Class II

Predicate Device Information :

Device Name	CardIQ Xpress 2.0 with SnopShot Freeze Option
Manufacturer	GE Medical System SCS (d.b.a GE Healthcare)
510(k) number	K120910 cleared on June 18, 2012
Regulation number /product Code	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

SnapShot Freeze 2 (SSF 2) is a post processing software, which can be delivered on general purpose computing platforms. SnapShot Freeze 2 is an automated motion correction algorithm designed for use with gated cardiac acquisitions from GE CT scanners to reduce cardiac induced motion artifacts in the whole heart. It is based on the same fundamental algorithm as the predicate product commercially marketed under the name CardIQ Xpress 2.0 with SnapShot Freeze Option (K120910, AKA SSF 1). Same as its predicate device the SSF 2 algorithm works on multi-phase, gated cardiac CT DICOM compatible image data and produces a new image series in which motion artifact is reduced.

The device is marketed as SnapShot Freeze 2

Intended Use

SnapShot Freeze 2 is intended to be used for motion correction of gated cardiac image series

Indications for Use

SnapShot Freeze 2 is designed for use with gated cardiac acquisitions to reduce cardiac induced motion artifacts.

Technological Characteristic

SSF 2 employs the same fundamentally technology as that of the predicate. The motion correction algorithm fundamentally remains the same, taking the multi-phase temporal enhanced cardiac gated DICOM series, applying motion correction and producing the dramatically motion reduced DICOM dataset. The difference is that the SSF2 extends the motion correction capability to the whole heart beyond the coronary vessels as offered in the predicate.

Comparisons

The most notable change in SSF 2 as compared to SSF1 is the ability to extend motion correction capability to the whole heart compared with only coronary vessel motion artifact reduction. This may enable new applications in assessing other structures of the heart that are impacted by motion artifacts.

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Specification/ Attribute	**Predicate Device** **CardIQ Xpress 2.0 with SnapShot Freeze Option (K120910)**	**Proposed Device** **SnapShot Freeze 2**
Patient Population	Patients referred for a CT cardiovascular examination	Same
Contraindications	None	Same
Platforms	AW workstation, AW Server & CT Console	AW workstation, AW Server, CT Console & other platforms including cloud-based computing and image processing platforms
Input	3-phase temporal cardiac image series	Same
Output	Motion corrected target phase image series	Same
Motion Correction of coronary vessels	Yes – SSF algorithm is capable of coronary vessel motion correction	Same
Whole heart motion correction	Not Available	Yes, enchantment to the algorithm demonstrates whole heart motion correction
Effective Temporal Resolution*	6x improvement in reducing blurring artifacts of the coronary arteries due to cardiac motion. Effective temporal resolution of 29 ms for 0.35 sec/rot gantry speed.	6x improvement in reducing blurring artifacts of the coronary arteries due to cardiac motion. Effective temporal resolution of 29 ms for 0.35 sec/rot gantry speed. Effective temporal resolution of 24 ms for 0.28sec/rot gantry.

*As demonstrated in mechanical and mathematical cardiac phantom testing.

SnapShot Freeze 2 does not introduce any new risks/hazards, warnings, or limitations.

Determination of Substantial Equivalence

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The testing used a commercially available cardiac motion phantom with linear motion of variable velocity for modeling of the coronary vessels and the whole heart. The testing also used a mathematical phantom to demonstrate effective temporal resolution, coronary motion and whole heart motion correction. The combination of both analyses (from physical and mathematical motion phantoms) is intended to provide further confidence in the capabilities and full extent of the Snapshot Freeze 2 whole heart motion correction.

A representative clinical sample image set of 60 CT cardiac cases, focused on patient populations with elevated heart rate were assessed by three board certified radiologists using 5-point Likert scale. This data is representative of routine clinical imaging from a cardiac acquisition perspective, but intentionally includes data from subjects with elevated heart rates or those with heart rate variability which represent more challenging cases, in which such an algorithm is most likely to be utilized. The assessment demonstrated the diagnostic capability of the motion corrected images by SSF 2.

SnapShot Freeze 2 has successfully completed the required design control testing per GE's quality system. No new hazards were identified, and no unexpected test results were obtained. SnapShot Freeze 2 was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures have been applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Software Development Lifecycle
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device using device-based respiratory gating.

The substantial equivalence was also based on software documentation for a "**Moderate**" level of concern device.

Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the SnapShot Freeze 2 is as safe and effective, and performs in a substantially equivalent manner to the predicate device CardIQ Xpress 2.0 with SnopShot Freeze Option.