GE Medical Systems, LLC.
℅ Ms. Amy Yang
Regulatory Affairs Manager
3000 N Grandview Blvd
WAUKESHA WI 53188

March 2, 2021

Re: K203617
Trade/Device Name: MaxFOV 2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 9, 2020
Received: December 11, 2020

Dear Ms. Yang:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203617

Device Name
MaxFOV 2

Indications for Use *(Describe)*

The deep learning based Max Field-of-View (MaxFOV 2) is a CT image reconstruction method intended to produce images of the head and whole-body using Axial, Helical, and Cine acquisitions.

MaxFOV 2 is designed to extend the nominal display field of view (DFoV) for cases where patient size and positioning requirements result in a portion of the patient's body to be outside of the nominal DFoV.

These extended FoV images are intended for use in radiation therapy planning and are clinically useful for the simulation and planning of radiation therapy for the treatment of cancer for patients. They can also be used for visualization of patient anatomy for cases not involving therapy planning. MaxFOV 2 is intended for patients of all ages, especially bariatric patients.

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:	December 10, 2020
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Amy Yang Regulatory Affairs Manager Phone: 414-514-3904 Email: Amy.yang@ge.com
Secondary Contacts:	John Jaeckle Chief Regulatory Affairs Engineer Phone: 262-424-9547 Email: john.jaeckle@ge.com
Device Trade Name:	MaxFOV 2
Device Classification	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name:	LightSpeed Ultra with Wide View Option
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K023332, Cleared on October 23, 2002
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Reference Devices Information

Device Name:	SOMATOM DEFINITION AS OPEN
Manufacturer:	Siemens Medical Systems, Inc.
510(k) Number:	K130901 cleared on January 02, 2014
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

The MaxFOV 2 is an enhanced Extended Field of View (EFOV) reconstruction option for GE's CT scanners. The MaxFOV 2 utilizes a new deep learning algorithm to extend the display field of view (DFOV) beyond the CT system's scan field of View (SFOV) of 50cm to up to 80cm depending on the bore size of the CT system. CT scanners use the EFOV reconstruction algorithms to visualize tissue truncated due to large patient habitus and/or off-center patient positioning. Same as the Wide View option on the predicate, the MaxFOV 2 is designed to enable a clinically useful visualization of the skin line and CT Number of human body parts located outside of the SFOV. EFOV images are especially useful for radiation therapy planning and they can also be used for visualization of patient anatomy outside of the SFOV for routine CT imaging. This DL enabled new MaxFOV2 EFOV reconstruction process offers improved performance over the existing WideView option on the predicate device.

The DL MaxFOV2 algorithm was designed and tested for GE's multiple CT scanner platforms of various bore sizes from 70cm to 80cm. These CT systems with the integrated MaxFOV 2 option remain compliant with the same standards as base CT systems.

This option is commercially marketed as MaxFOV2.

Intended Use

The MaxFOV 2 reconstruction software is intended for head and whole body CT scans.

Indications for Use

The deep learning based Max Field-of-View (MaxFOV 2) is a CT image reconstruction method intended to produce images of the head and whole-body using Axial, Helical, and Cine acquisitions.

MaxFOV 2 is designed to extend the nominal display field of view (DFoV) for cases where patient size and positioning requirements result in a portion of the patient's body to be outside of the nominal DFoV.

These extended FoV images are intended for use in radiation therapy planning and are clinically useful for the simulation and planning of radiation therapy for the treatment of cancer for patients. They can also be used for visualization of patient anatomy for cases not involving therapy planning. MaxFOV 2 is intended for patients of all ages, especially bariatric patients.

Technological Characteristics

The MaxFOV 2 employs the same fundamental technology as that of the WideView on the predicate device. It is used in the same clinical environment and by the same intended users. Use of the MaxFOV2 does not require change in the CT scanner hardware and does not alter the CT system's control mechanism, or energy type or operating principles.

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

Specification	Predicate Device Wide View (K023332)	Proposed Device MaxFOV 2
Patient Population	Patients of all ages	Same
Intended users	Dosimetrist Medical Physicists Radiation Oncologists	Same
Clinical Use	Routine Clinical Use	Same
Targeted clinical condition, anatomy	Part of scanned object is located out of the scan field of view.	Same
Compatible Scan modes	Compatible with Axial, Helical, and Cine scan modes.	Same
Technology/Principles	Analytical model – classic algorithm where the measured sinogram is expanded to cover a FOV larger than SFOV.	MaxFOV 2 uses a CNN which is trained on multiple CT scanners. MaxFOV 2's reconstruction process (algorithm) contains a Deep Learning based component.
Extended Field of View Spec	Allows visualization of up to 65cm	Allows visualization of up to 80cm, same as reference device

The MaxFOV 2 option has same intended use, indications for use and substantially equivalent technological characteristics as its predicate and reference device. The changes and the different technological characteristics do not raise new or different questions of safety and effectiveness. The software was developed, verified, and validated under GE Healthcare's QMS including software development lifecycle.

Determination of Substantial Equivalence
Summary of Non-Clinical Testing

MaxFOV 2 has successfully completed the design control activities per our quality system that conforms to the Quality System Regulations of 21CFR 820 and ISO 13485, including the Software Development Life Cycle process per IEC62304.

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)

A suite of engineering bench testing using phantoms was performed to evaluate image quality performance of MaxFOV 2. These tests include:

- MaxFOV 2 Patient contour (Skin line) accuracy and CT Number accuracy
- MaxFOV 2 IQ Performance Evaluation using a very large phantom
- MaxFOV 2 Performance Evaluation Using an anthropomorphic phantom

This set of testing was repeated and performed on different GE CT system platforms, all test results demonstrated MaxFOV 2's consistent and acceptable performance.

The complete testing and results did not raise different questions of safety and effectiveness than associated with predicate device. We consider the proposed device is substantially equivalent to the predicate and reference devices, and hence is safe and effective for its intended use.

Summary of Clinical Testing

A clinical reader study with 49 CT exams was conducted. The exams were acquired from different GE CT system platforms and were scored by 5 external, clinical readers. The exams represent typical and challenging RTP-relative scenarios where the MaxFOV2 will likely be used. The readers used a 5 point Likert scale to score the images for each of the following aspects: depiction of the patient's skin surface; depicted tissue densities in the extended FOV region; and overall image quality. The results of the study support substantial equivalence and performance claims.

Substantial Equivalence

MaxFOV 2 was developed under GE Healthcare's quality system. MaxFOV2's design, verification, validation and risk management processes did not identify any new hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Software verification & validation, along with bench testing and the clinical reader study demonstrate that MaxFOV 2 is substantially equivalent and hence as safe and as effective as the legally marketed predicate device, hence is safe and effective for its intended use.

The substantial equivalence is also based on the submitted software documentation that is consistent with the appropriate Level of Concern as recommended by pre-market software guidance.

Conclusion

Based on development under GE Healthcare's quality system, the successful verification and validation, engineering bench and clinical testing, GE Healthcare believes that MaxFOV 2 is substantially equivalent to the predicate device and hence is safe and effective for its intended use.