GE Healthcare
% Mr. George Mashour
Regulatory Affairs Manager
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

March 29, 2021

Re: K210173
Trade/Device Name: StarGuide
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: January 21, 2021
Received: January 22, 2021

Dear Mr. Mashour:

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)*
K210173

Device Name
StarGuide

Indications for Use *(Describe)*
The GE StarGuide system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders, orthopedic disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy, including the nuclear medicine part of theragnostic procedures. The GE StarGuide system, combining a CZT-based, high energy and spatial resolution, Nuclear Medicine (NM) system and a Computed Tomography (CT) system, is intended to produce:

• NM System: General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using tomographic scanning of single or multi-isotopes with either single or multi energy peaks. The tomographic scanning is supported by various acquisition types and by imaging features designed to enhance image quality.

• CT System: Cross sectional images of the body by computer reconstruction of X-Ray transmission data taken at different angles and planes, including Axial, Cine, Helical, Cardiac, and Gated acquisitions. These images may be obtained with or without contrast. The CT system is indicated for head, whole body, cardiac and vascular X-Ray Computed Tomography applications.

• NM + CT System: Combined, hybrid SPECT and CT protocols, for CT-based corrections of SPECT images as well as functional and anatomical mapping imaging (localization, registration and fusion).

The GE StarGuide system includes digital processing of data and images, signal analysis and display equipment, patient and equipment supports, components and accessories. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation. The system may be used for patients of all ages.

FAME: Functional-Anatomical Mutual Enhancement (FAME) technology is an image processing method intended for Computed Tomography (CT) based corrections of Nuclear Medicine (NM) bone scintigraphy images. FAME adjusts the radioisotope tracer distribution to correlate with the skeletal anatomical structures in the CT image. FAME may be used 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.

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Section 5: 510(k) Summary

StarGuide

510(k) SUMMARY OF SAFETY AND EFFECTIVNESS

K210173

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

Date: January 21, 2021

Submitter: GE Medical Systems Israel, Functional Imaging (GE Healthcare)
4 Hayozma Street
Tirat Hacarmel, 30200, Israel

Primary Contact: George Mashour
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Device Trade Name: StarGuide

Device Classification: Class II

Regulation Number: 21CFR 892.1200 & 21CFR 892.1750

Product Codes: 90 KPS & 90 JAK

Predicate Device Information	
Device Name:	Discovery NM/CT 670 CZT
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K153402
Regulation Number/ Product Code:	21CFR 892.1200 & 21CFR 892.1750 90 KPS & 90 JAK

Reference Device Information	
Device Name:	NM/CT 850 and NM/CT 860
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K173816
Regulation Number/ Product Code:	21CFR 892.1200 & 21CFR 892.1750 90 KPS & 90 JAK

Reference Device Information	
Device Name:	Veriton CT
Manufacturer:	Spectrum Dynamics Medical Ltd
510(k) Number:	K182484
Regulation Number/ Product Code:	21CFR 892.1200 & 21CFR 892.1750 90 KPS & 90 JAK

Marketed Devices

StarGuide is a modification of the predicate device, Discovery NM/CT 670 CZT. The primary changes are related to replacing the dual head CZT detector NM system on Discovery NM/CT 670 CZT with a new, SPECT acquisition-only NM system that uses twelve, slim CZT detectors that are uniformly distributed around the gantry bore. The CT portion of the StarGuide system remains untouched.

Device Description

StarGuide is a SPECT-CT system that combines an all-purpose Nuclear Medicine imaging system and the commercially available GE Optima CT540 CT system. It is intended for general purpose Nuclear Medicine (NM) imaging procedures as well as head, whole body, cardiac and vascular CT applications and CT-based corrections and anatomical localization of SPECT images. The StarGuide system does not introduce any new Intended Use.

Each of StarGuide's twelve CZT detectors can independently rotate about their long axis and "sweep" the field of view (FOV). The detectors can also move rotationally around the gantry and radially in and out, similar to that of the reference device, Spectrum Dynamics' Veriton CT. The detectors on StarGuide's NM system are built up from the identical same CZT modules that are used in the current production version of the predicate device.

StarGuide's table is the same as the one used on the NM/CT 850 and NM/CT 860 reference systems with only slight modifications. StarGuide's "SmartConsole" is the same as that on the NM/CT 850 and NM/CT 860 with modifications made primarily in support of StarGuide image processing. StarGuide's image processing (i.e. reconstruction and post reconstruction processing) uses known algorithms and methods that have been cleared for emission computed tomography (i.e. SPECT, PET). However, StarGuide introduces a new post reconstruction image processing algorithm, FAME, for CT-based correction of NM bone scintigraphy images for better correlation with the skeletal anatomical structures in the CT image.

Intended Use

The GE StarGuide system is intended for general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body. It includes a general purpose Nuclear Medicine system using tomographic scanning mode supported by various acquisition types, and a Computed Tomography system which is intended for enabling CT-based corrections and anatomical localization of SPECT images and for standalone head, whole body, cardiac and vascular X-ray Computed Tomography applications.

FAME: The Functional-Anatomical Mutual Enhancement (FAME) technology is an image processing method for Nuclear Medicine (NM) bone scintigraphy images.

Indications for Use

The GE StarGuide system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders, orthopedic disorders, and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy, including the nuclear medicine part of theragnostic procedures. The GE StarGuide system, combining a CZT-based, high energy and spatial resolution, Nuclear Medicine (NM) system and a Computed Tomography (CT) system, is intended to produce:

- ***NM System:*** *General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using tomographic scanning of single or multi-isotopes with either single or multi energy peaks. The tomographic scanning is supported by various acquisition types and by imaging features designed to enhance image quality.*
- ***CT System:*** *Cross sectional images of the body by computer reconstruction of X-Ray transmission data taken at different angles and planes, including Axial, Cine, Helical, Cardiac, and Gated acquisitions. These images may be obtained with or without contrast. The CT system is indicated for head, whole body, cardiac and vascular X-Ray Computed Tomography applications.*
- ***NM + CT System:*** *Combined, hybrid SPECT and CT protocols, for CT-based corrections of SPECT images as well as functional and anatomical mapping imaging (localization, registration and fusion).*

The GE StarGuide system includes digital processing of data and images, signal analysis and display equipment, patient and equipment supports, components and accessories. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation. The system may be used for patients of all ages.

FAME: Functional-Anatomical Mutual Enhancement (FAME) technology is an image processing method intended for Computed Tomography (CT) based corrections of Nuclear Medicine (NM) bone scintigraphy images. FAME adjusts the radioisotope tracer distribution to correlate with the skeletal anatomical structures in the CT image. FAME may be used for patients of all ages.

Technological Characteristics

StarGuide and its predicate use the same principles of SPECT acquisitions. The two systems rotate the detectors around the patient to acquire projections from multiple angular positions and reconstruct them into a SPECT image. The difference is that the detectors on StarGuide acquire the projections using a sweeping motion. Because of the multiple projections acquired with sweep motion at each rotational angular position, StarGuide SPECT scans require fewer angular positions than dual detector NM systems. The sweep motion allows SPECT scans to be acquired either uniformly over the sweep's full range or "focused" on a user-defined region of interest (ROI).

StarGuide automates the setup of SPECT scans for enhancements in workflow and scan motion efficiency. Based on a user-defined linear range (in the z direction), the system determines the contour of the patient's body and cradle and combines it with protocol-specific settings to plan the systems and detectors' motion and position during SPECT scans, without additional user intervention.

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

Subsystem / Specification	**Predicate Device** **Discovery NM/CT 670 CZT (K153402)**	**Proposed Device** **StarGuide**
NM Gantry	Dual CZT detectors for Planar and SPECT Imaging 70 cm bore	Twelve CZT detectors for SPECT Imaging 80 cm bore
NM Detectors	Built using CZT modules Rotational and radial motion.	Built using the identical CZT modules Rotational, radial, and sweep motion.
NM Collimators	Wide Energy High Resolution (WEHR) Medium Energy High Resolution and Sensitivity (MEHRS)	Fixed Collimator
Energy Range	40 – 250 keV	40 – 270 keV
Energy Resolution	≤ 6.3% for Tc-99m @ 20 kcps	≤ 5.9% for Tc-99m @ 20 kcps
SPECT Reconstructed Spatial Resolution with Scatter	Central: ≤ 6.0 mm Radial: ≤ 5.5 mm Tangential: ≤ 4.1 mm *with WEHR collimator	Central: ≤ 4.5 mm Radial: ≤ 4.1 mm Tangential: ≤ 3.2 mm
Automated Patient Contouring	Yes	Yes
CT System	Optima CT540, 16 channel CT system	Identical
Standards Conformance	IEC 60601-1 and applicable Collateral and Particular Standards.	Identical
Image Processing	Xeleris Workstation	Xeleris Workstation and Smart Console
Software Level of Risk	Moderate	Moderate

StarGuide's technological characteristics do not create new questions of safety or effectiveness, and did not introduce any new risks/hazards, warnings, or limitations.

Determination of Substantial Equivalence

Summary of Non-Clinical, Design Control Testing

StarGuide has successfully completed the design control testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. StarGuide was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. GE believes that the extensive bench testing and the physician evaluations performed are sufficient for FDA's substantial equivalence determination.

StarGuide has been independently tested and conforms with IEC 60601-1 Ed. 3.1 and its applicable Collateral and Particular Standards.

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

- Requirement Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Testing on unit level (Module verification)
- Integration testing (System verification)
- System Testing:
  - Safety Testing (Verification)
  - System and Image Performance Testing (Verification)
  - Simulating Use Testing (Validation)

The testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device. We consider the proposed device is substantially equivalent to the predicate device.

The substantial equivalence is also based on the software documentation for a "Moderate" level of concern. GE believes that StarGuide is of comparable type and substantially equivalent to the predicate device.

Additional Non-Clinical Testing

Engineering bench testing was performed to support substantial equivalence, demonstrate performance, and substantiate the product claims. This included testing for:

- SPECT resolution
- Planar & volume sensitivity
- Energy resolution and simultaneous multi-isotope acquisition
- Count rate linearity
- Temporal resolution for dynamic SPECT

- Body contour & adaptive motion planning
- Focused imaging acquisitions
- Contrast to noise ratio
- Lutetium-177 imaging performance
- Lesion detectability when using FAME
- Patient contact safety
- Generation of derived planar images

Clinical Testing

A clinical reader study using 42 SPECT CT exams acquired in StarGuide was conducted at two clinical sites. The exams constituted a clinically representative sample for evaluation of StarGuide's performance. The results of the study support the determination of substantial equivalence. In total five experienced NM physicians scored the images using 5 point Likert scales for both overall image quality and image resolution. All of the physicians attested that their assessments demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion

The changes associated with StarGuide do not create a new Intended Use and represent equivalent technological characteristics, with no impact on the control mechanisms, operating principle, and energy type. GE's quality system's design verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE Healthcare's quality system, the successful system and software verification and validation testing, conformance to standards, the additional engineering bench testing, and the clinical reader study demonstrates that StarGuide is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.