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

August 27, 2021

Re: K212004
Trade/Device Name: MyoSPECT, MyoSPECT ES
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: June 24, 2021
Received: June 28, 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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212004

Device Name
MyoSPECT
MyoSPECT ES

Indications for Use *(Describe)*

The GE MyoSPECT and MyoSPECT ES systems are a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of cardiac diseases and heart function for the evaluation of diseases, abnormalities, and disorders. The systems output can also be used by the physician for planning, guiding, and monitoring.

MyoSPECT and MyoSPECT ES perform Nuclear Medicine (NM) imaging procedures for the 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.

The GE MyoSPECT and MyoSPECT ES systems include signal analysis and display equipment, patient and equipment supports, components and accessories. The systems may include data and image processing to produce reconstructed trans-axial images. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation.

The systems 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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510(k) SUMMARY

K212004

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

Date: June 24th, 2021

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

Primary Contact: George Mashour
Regulatory Affairs Manager
GE Medical Systems Israel, Functional Imaging
Tel: +972-4-8563666 ext. 639
Email: george.mashour@ge.com

Secondary Contact: John Jaeckle
Chief Regulatory Affairs Engineer and Strategist
GE Healthcare
Tel: 262-424-9547
email: john.jaeckle@ge.com

Device Trade Name: MyoSPECT
MyoSPECT ES

Device Classification: Class II

Regulation Number: 21CFR 892.1200

Product Codes: 90 KPS

Predicate Device Information	
Device Name:	Ventri 1.1
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K080124
Regulation Number / Product Code:	21CFR 892.1200 90 KPS

Note: The current production of Ventri 1.1 is commercially named Discovery NM 530c. Through this summary, the commercial name Discovery NM 530c is used to refer to the predicate device.

Reference Device Information	
Device Name:	Discovery NM 630
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K111445
Regulation Number/ Product Code:	21CFR 892.1200 90 KPS

Note: The current production of Discovery NM 630 is commercially named NM 830. Through this summary, the commercial name NM 830 is used to refer to the reference device.

Marketed Devices

MyoSPECT and MyoSPECT ES are a modification to the predicate Discovery NM 530c. The primary changes are the introduction of nine (9) detectors configuration on MyoSPECT ES, an option for Extended Field of View (EFOV) processing, enhanced patient positioning workflow, and replacing the patient table with the patient table from the reference NM 830 device. A nineteen (19) detector configuration remains on MyoSPECT, as the current production version of the predicate device.

Device Description

The GE MyoSPECT and MyoSPECT ES are Single Photon Emission Computed Tomography (SPECT) systems intended for nuclear cardiology imaging. MyoSPECT and MyoSPECT ES include a nuclear medicine imaging system using a CZT-based multi-detector array. MyoSPECT and MyoSPECT ES are identical systems that are differentiated by the number of detectors within the multi-detector array. MyoSPECT is offered with 19 detectors as opposed to 9 detectors for MyoSPECT ES. MyoSPECT ES is upgradable to MyoSPECT. The MyoSPECT and MyoSPECT ES systems do not introduce any new Intended Use.

The multi-detector array on MyoSPECT and MyoSPECT ES has a multi-pinhole collimator providing each detector with a pinhole collimator that is focused on a volume in space, all together forming the Quality Field of View (Q.FOV) in which the patient heart is positioned for a cardiac scan.

MyoSPECT and MyoSPECT ES add an option for Extended Field of View (EFOV) processing that enables more flexible positioning. The predicate device patient positioning workflow is also enhanced to provide users with visual means of the Q.FOV and EFOV boundaries, and recommendations on the use of Q.FOV

or EFOV. The enhanced workflow is named "Smart Positioning" workflow. MyoSPECT's and MyoSPECT ES's patient table is the same as the one used on the NM 830 reference device with slight adaptations.

Intended Use

The GE MyoSPECT and MyoSPECT ES systems are intended for Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body. MyoSPECT and MyoSPECT ES include a Nuclear Medicine system using tomographic scanning mode supported by various acquisition types.

Indications for Use

The GE MyoSPECT and MyoSPECT ES systems are a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing and diagnosing of cardiac diseases and heart function for the evaluation of diseases, abnormalities, and disorders. The systems output can also be used by the physician for planning, guiding, and monitoring.

MyoSPECT and MyoSPECT ES perform Nuclear Medicine (NM) imaging procedures for the 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.

The GE MyoSPECT and MyoSPECT ES systems include signal analysis and display equipment, patient and equipment supports, components and accessories. The systems may include data and image processing to produce reconstructed trans-axial images. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation.

The systems may be used for patients of all ages.

Technological Characteristics

MyoSPECT and MyoSPECT ES employ the same fundamental scientific technology as the predicate and reference devices. The three systems share the same CZT multi-detector array, except for difference in the number of detectors within the array. The detectors acquire projections simultaneously, without system motion. The acquired projections are processed into trans-axial images using the same methods for the three systems. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Subsystem / Specification	**Predicate Device** **Discovery NM 530c (K080124)**	**Proposed Device** **MyoSPECT, MyoSPECT ES**
Gantry	Multi-detector array gantry for SPECT imaging. 70 cm bore.	Multi-detector array gantry for SPECT imaging. 70 cm bore.
Detection	Multi-detector array 19 CZT Detectors	Multi-detector array 19 CZT Detectors (MyoSPECT) 9 CZT Detectors (MyoSPECT ES)
Collimator	Multi-Pinhole Collimator	Multi-Pinhole Collimator
Field of View	Q.FOV	Q.FOV Extended FOV
Energy Range	40 -200 keV	60 -200 keV
Energy Resolution	Tc99m FWHM ≤ 7.0%	Tc99m FWHM ≤ 6.2%
Patient Positioning Workflow	Yes	Yes
Standards Conformance	IEC 60601-1 and applicable Collateral and Particular Standards.	IEC 60601-1 and applicable Collateral and Particular Standards.
Image Processing	Xeleris Workstation	Xeleris Workstation and Smart Console
Software Level of Risk	Moderate	Moderate

MyoSPECT's and MyoSPECT ES'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

MyoSPECT and MyoSPECT ES have successfully completed the design control testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. MyoSPECT and MyoSPECT ES were 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.

MyoSPECT and MyoSPECT ES have 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 MyoSPECT and MyoSPECT ES 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
- Image Uniformity and Contrast
- Energy resolution and simultaneous multi-isotope acquisition
- Extended Field of View
- Smart Positioning Q.FOV / EFOV Workflow

Clinical Testing

A clinical reader study using 28 studies for MyoSPECT and 32 studies for MyoSPECT ES was performed by three experience NM physicians. The exams constituted a clinically representative sample for evaluation of MyoSPECT's and MyoSPECT ES's performance. The results of the study support the determination of substantial equivalence. The three experienced NM physicians scored the images using 5-point Likert scales for overall image quality. All the physicians attested that their assessments demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion

The changes associated with MyoSPECT and MyoSPECT ES 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 MyoSPECT and MyoSPECT ES are substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.