GE Healthcare
GE Medical Systems Israel, Functional Imaging
% Mr. George Mashour
Senior Regulatory Affairs Leader
4 Hayozma Street
Tirat Hacarmel 30200
ISRAEL

April 17, 2018

Re: K173816
Trade/Device Name: NM/CT 850, NM/CT 860
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: March 8, 2018
Received: March 9, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*

K173816

Device Name
NM/CT 850 NM/CT 860

Indications for Use *(Describe)*

The GE NM/CT 850 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in the assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors; and planning, guiding, and monitoring therapy.

NM System: General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). Imaging modes include single photon, multi-isotope, and multi peak frame, with data stored frame/list mode. The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

CT System: Intended specifically for attenuation correction and anatomical localization.

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

The GE NM/CT 850 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include digital processing of data and images, including display, quality check, transfer, and processing, to produce images in a variety of trans-axial and reformatted planes. 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.

NM/CT 850 does not support standalone CT operation.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K173816

Device Name
NM/CT 860

Indications for Use *(Describe)*
The GE NM/CT 860 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in the assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors; and planning, guiding, and monitoring therapy.

NM System: General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT), Imaging modes include single photon, multi-isotope, and multi-peak, with data stored in frame/list mode. The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

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

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

The GE NM/CT 860 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include digital processing of data and images, including display, quality check, transfer, and processing, to produce images in a variety of trans-axial and reformatted planes., 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.

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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:	December 14, 2017
Submitter:	GE Medical Systems Israel, Functional Imaging (GE Healthcare) 4 Hayozma Street Tirat Hacarmel, 30200, Israel
Primary Contact:	George Mashour Regulatory Affairs Leader GE Medical Systems Israel, Functional Imaging Tel: +972-4-8563666 ext. 639 Fax: +972-4-8577662 email: george.mashour@ge.com
Secondary Contacts:	John Jaeckle Chief Regulatory Affairs Engineer GE Healthcare Tel: 262-424-9547 email: john.jaeckle@ge.com
Device Trade Name:	NM/CT 850 NM/CT 860
Common / Usual Name:	Single Photon Emission Computed Tomography (SPECT) & Computed Tomography X-Ray (CT)
Classification Names:	21CFR 892.1200 & 21CFR 892.1750
Product Code:	90 KPS & 90 JAK

Marketed Devices

NM/CT 850 and NM/CT 860 are a modification to the predicate device Discovery NM/CT 670 (K093514). The modification is mainly for replacing the CT subsystem with GE's 8 slice Revolution ACTs (K171013), incremental NM Image Quality (IQ) enhancement and addition of a Smart Console for enhanced workflow and accessibility. All the rest of system remains the same as in Discovery NM/CT 670 (K093514) and has equivalent functionality and performance.

The systems are marketed as NM/CT 860 and NM/CT 850.

Predicate Device(s):

Discovery NM/CT 670 (K093514)

Reference Device

Optima NM/CT 640 (K121019)

Revolution ACTs (K171013)

Xeleris 4.0 Workstation (K153355)

Device Description:

NM/CT 850 and NM/CT 860 consist of 2 back-to-back gantries (i.e. NM gantry carrying 2 nuclear detectors and a CT gantry), patient table, power distribution unit (PDU), operator console with two acquisition systems (i.e. NM and CT) and a digital processing system, interconnecting cables and associated accessories.

NM/CT 850 and NM/CT 860 generate NM images and CT-based attenuation correction and anatomical localization data for SPECT imaging. NM/CT 860 also generates diagnostic CT images. The NM images are generated through computer reconstruction of data acquired by a NaI-based dual detector NM system that uses a variety of planar and tomographic acquisition types. The CT images are generated by computer reconstruction of data acquired using the Revolution ACTs CT system.

The main technological differences between the CT system of the predicate Discovery NM/CT 670 device and that of the proposed NM/CT 850 and NM/CT 860 devices, are as following:

Aspect	Discovery NM/CT 670 (K093514)	NM/CT 860 NM/CT 850
Rotation Speed	0.8, 1.0, 2.0, 3.0, 4.0 sec	0.98, 1.0, 1.2, 1.5, 2.0, 3.0, 4.0 sec.
Available kV	80, 100, 120, 140 kV	80, 100, 120, 140 kV
Tube Current	10-440 mA	10-200 mA (NM/CT 860) 10-30 mA (NM/CT 850)
Detector Composition	16 x 0.625 mm rows with 4 x 1.25 mm rows on either side	8 x 1.25 mm rows

Slices per rotation	16	8
Max Beam Width	20 cm	10 cm
Bore	70 cm	70 cm
SFOV	50 cm	50 cm

Intended Use:

NM/CT 850

The GE NM/CT 850 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 a variety of scanning modes supported by various acquisition types, and a Computed Tomography component which is intended specifically for enabling attenuation correction and anatomical localization of SPECT images.

NM/CT 860 Intended Use

The GE NM/CT 860 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 a variety of scanning modes supported by various acquisition types, and a Computed Tomography system which is intended for enabling attenuation correction and anatomical localization of SPECT images and for standalone head, whole body and vascular X-ray Computed Tomography applications

Indications for Use:

NM/CT 850

The GE NM/CT 850 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in the assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors; and planning, guiding, and monitoring therapy.

- **NM System:** General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). Imaging modes include single photon, multi-isotope, and multi peak frame, with data stored frame/list mode.

The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

- **CT System:** Intended specifically for attenuation correction and anatomical localization.
- **NM + CT System:** Combined, hybrid SPECT and CT protocols, for CT-based SPECT attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration, and fusion).

The GE NM/CT 850 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include digital processing of data and images, including display, quality check, transfer, and processing, to produce images in a variety of trans-axial and reformatted planes. 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.

NM/CT 850 does not support standalone CT operation

NM/CT 860

The GE NM/CT 860 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in the assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors; and planning, guiding, and monitoring therapy.

- **NM System:** General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT), Imaging modes include single photon, multi-isotope, and multi-peak, with data stored in frame/list mode. The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.
- **CT System:** produces Cross sectional images of the body by

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

- **NM + CT System:** Combined, hybrid SPECT and CT protocols, for CT-based SPECT attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration, and fusion).

The GE NM/CT 860 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include digital processing of data and images, including display, quality check, transfer, and processing, to produce images in a variety of trans-axial and reformatted planes., 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.

Technology:

NM/CT 850 and NM/CT 860 employ the same fundamental scientific technology as the predicate device Discovery NM/CT 670 (K093514) and the reference devices, Optima NM/CT 640 (K121019), Revolution ACTs (K171013) and Xeleris 4.0 Workstation (K153355).

Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

NM/CT 850 and NM/CT 860 have completed testing and is in compliance with IEC 60601-1 Ed. 3.1 and its associated collateral and particular standards, 21CFR Subchapter J and the relevant NEMA standards, including XR-25, XR-26, XR-28, PS3.1-3.20 and NU-1

The device has successfully completed all design control testing per our quality system. No new hazards were identified and no unexpected test results were obtained. The NM/CT 850 and NM/CT 860 were designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were 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)

GE believes the NM/CT 850 and NM/CT 860 systems are of comparable type and substantially equivalent to the predicate (i.e. Discovery NM/CT 670) and reference (i.e. Optima NM/CT 640, Revolution ACTs and Xeleris 4.0) devices, and hence is safe and effective for its intended use. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing:

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (i.e. non-clinical testing) was performed to provide the requisite data to substantiate performance, claims, and, ultimately substantial equivalence.

Non-Clinical Testing

The additional engineering performance evaluation testing used a variety of test methods and phantoms appropriate for the performance metric/claim that was to be tested and evaluated. Mathematical and physics analysis were performed to demonstrate that each performance metric/claim was successfully verified and substantiated.

The areas additionally evaluated for the non-clinical testing included system sensitivity, system resolution, lesion detectability and potential for dose / time reduction. The lesion detectability evaluation included use of a Channelized Hotelling Model Observer (CHO) study. The potential for dose/time reduction is demonstrated in phantom testing with a bone scan protocol using the CHO model observer to obtain equivalent AUC/SNR at the reduced dose/time. The model observer is shown to have significant positive correlations with the rankings of an average human observer[1].

[1]Gifford, Howard C., Michael A. King, Daniel J. de Vries, and Edward J. Soares. "Channelized Hotelling and human observer correlation for lesion detection in hepatic SPECT imaging." J. Nucl. Med. vol. 41, no. 3, pp. 514-521, March 2000.

Clinical Testing

Because the changes associated with NM/CT 850 and NM/CT 860 do not change the Indications for Use from the predicate and reference devices, and represent equivalent technological characteristics, this

type of change supports using scientific, established / standardized, engineering/physics-based performance testing, without inclusion of clinical images for determining substantial equivalence.

Given the above information and the type and scope of changes, particularly that the NM imaging component is identical to the predicate, and the CT component is virtually identical to the Revolution ACTs reference device, clinical testing is not needed to demonstrate substantial equivalence.

Conclusion: Based on the conformance to standards, development under GE Healthcare's quality system, the successful verification testing, and the additional engineering testing, GE Healthcare believes that the NM/CT 850 and NM/CT 860 are substantially equivalent to the predicate (i.e. Discovery NM/CT 670) and reference (i.e. Optima NM/CT 640, Revolution ACTs and Xeleris 4.0) devices, and hence is safe and effective for their intended use.