January 17, 2025

GE Medical Systems Israel, Functional Imaging
Hanne Jubran
Senior Regulatory Affairs Leader
(GE Healthcare)
4 Hayozma Street
Tirat HaCarmel, 30200
Israel

Re: K243605
Trade/Device Name: Aurora
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: November 21, 2024
Received: November 21, 2024

Dear Hanne Jubran:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243605

Device Name

Aurora

Indications for Use *(Describe)*

The Aurora 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, including the nuclear medicine part of theragnostic procedures.

• 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, Helical (Volumetric), 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 SPECT attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration, and fusion).

The Aurora 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K243605

510(k) Summary

Aurora

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: November 21, 2024

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

Primary Contact: Hanne Jubran
Senior Regulatory Affairs Leader
GE Healthcare
Tel: +972-4-8563666
Fax: +972-4-8577662
email: hannejubran@gehealthcare.com

Secondary Contacts: George Mashour
Senior Regulatory Affairs Manager
GE Healthcare
Tel: +974-54-7464808
email: George.Mashour@gehealthcare.com

Device Trade Name: Aurora

Device Classification: Class II

Regulation Number 21CFR 892.1200 & 21CFR 892.1750

Product Code: KPS & JAK

Predicate Device Information	
Device Name	Discovery NM/CT 670
Manufacturer	GE Medical Systems Israel, Functional Imaging
510(k) number	K093514
Regulation number	21CFR 892.1200 and 21CFR 892.1750
Product Code	KPS and JAK

Reference Device Information	
Device Name	Revolution Ascend
Manufacturer	GE Healthcare Japan Corporation
510(k) number	K213938
Regulation number	21CFR 892.1750
Product Code	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	21CFR 892.1200 and 21CFR 892.1750
Product Code	KPS and JAK

Reference Device Information	
Device Name	Xeleris V Processing and Review System
Manufacturer	GE Medical Systems Israel, Functional Imaging
510(k) number	K221680
Regulation number	21CFR 892.2050
Product Code	LLZ

Marketed Device

GE HealthCare's (GEHC) subject Aurora device is a modification to the predicate Discovery NM/CT 670 device (K093514), replacing the 16-slice Optima CT540 CT sub-system with the more advanced 64-slice GEHC Revolution Ascend CT system (K213938). Aurora also introduces modifications intended to enhance workflow and patient comfort, including patient table with extended SPECT-CT scan range and a new "Realtime Time Activity Curve" software option for live monitoring of radiopharmaceutical uptake and clearance in target organs during NM planar dynamic imaging. The NM sub-system is carried on from the predicate device, while adding incremental updates from the NM/CT 850 and NM/CT 860 (K173816) reference devices. The software of the proposed Aurora is also developed from that of the predicate.

Device Description

GEHC's Aurora is a SPECT-CT system that combines an all-purpose Nuclear Medicine imaging system and the commercially available Revolution Ascend system. It is intended for general purpose Nuclear Medicine imaging procedures as well as head, whole body, cardiac and vascular CT applications and CT-based corrections and anatomical localization of SPECT images. Aurora does not introduce any new Intended Use.

Aurora consists of two back-to-back gantries (i.e. one for the NM sub-system and another for the CT subsystem), patient table, power distribution unit (PDU), operator console with a computer for both the NM acquisition and SmartConsole software and another for the CT software, interconnecting cables, and associated accessories (e.g. NM collimator carts, cardiac trigger monitor, head holder). The CT sub-system main components include the CT gantry, PDU, and CT operator console. All components are from the commercially available GEHC Revolution Ascend CT system. The CT gantry has been adapted for use with predicate device's NM portion. CT PDU, CT Console Keyboard and CT operator console are the same as in Revolution Ascend Plus.

Intended Use

The Aurora 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, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use

The Aurora 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, including the nuclear medicine part of theragnostic procedures.

- *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, Helical (Volumetric),*

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 SPECT attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration, and fusion).*

The Aurora 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.

Technological Characteristics

The proposed Aurora device employs the same fundamental scientific technology as the predicate device Discovery NM/CT 670 (K093514) and the reference devices, Revolution Ascend (K213938), NM/CT 850 and NM/CT 860 (K173816) and Xeleris V Processing and Review System (K221680).

The table below summarizes the substantive feature / technological differences between the predicate and proposed devices.

Specification / Attribute	**Predicate Device:** **Discovery NM/CT 670 (K093514)**	**Proposed Device:** **Aurora**
NM System	Dual NaI-based detectors NM system for Planar and SPECT imaging	Dual NaI-based detectors NM system for Planar and SPECT imaging, **with a new "Real-time Time Activity Curve" option for Planar Dynamic Scans**
CT System	GEHC Commercially Available Optima CT540 (K192686)	GEHC Commercially Available **Revolution Ascend (K213938)**
Patient Table	Dual axis table for Planar, SPECT, CT and SPECT / CT Imaging SPECT Scan Range: 200cm SPECT-CT Scan Range: 160 cm	Dual axis table for Planar, SPECT, CT and SPECT / CT Imaging SPECT Scan Range: 200cm SPECT-CT Scan Range: **185 cm**
Standards Conformance	IEC 60601-1 and applicable Collateral and Particular Standards.	IEC 60601-1 and applicable Collateral and Particular Standards.

Aurora'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

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

Aurora has been independently tested and conforms with IEC 60601-1 and its applicable Collateral and Particular Standards including IEC 60601-1-2, 60601-1-3, 60601-2-44, as well as performance testing per NEMA NU-1.

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

- Risk Analysis
- Required Reviews
- Design Reviews
- 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 new or different questions of safety and effectiveness than associated with predicate device. GE believes the proposed Aurora is of comparable type and substantially equivalent to our currently marketed system Discovery NM/CT 670 (K093514).

Summary of Additional Non-Clinical Testing:

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering bench testing (i.e. non-clinical testing) was performed to support substantial equivalence, demonstrate performance, and substantiate the product claims. 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. The additionally evaluated areas included applicability of cleared lesion detectability and dose / time reduction claims, quantitation accuracy, IQ performance with low dose CT for attenuation correction, and workflow.

Clinical Testing

Because the changes associated with Aurora 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 the commercially available Revolution

Ascend CT system, clinical images are not included in this submission. Clinical images are not needed to demonstrate substantial equivalence. The bench testing included in this submission and other submitted data / information, demonstrates that the Aurora is substantially equivalent and hence as safe and as effective as the legally marketed predicate and reference devices.

Substantial Equivalence Conclusion:

The modifications associated with proposed Aurora do not create a new Intended Use or Indications for Use and represent equivalent technological characteristics, with no changes to the control mechanisms, operating principle, and energy type. GEHC'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 GEHC's quality system, the successful system and software verification and validation testing, conformance to standards, and the additional engineering bench testing demonstrate that the proposed Aurora is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.