March 23, 2026

GE Healthcare Japan Corporation
% Yonghui Han
Senior Regulatory Affairs Leader
7-127, Asahigaoka, 4-Chome
Hino-Shi, TOKYO, 191-8503
JAPAN

Re: K253686
Trade/Device Name: True Definition DL
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 20, 2026
Received: February 20, 2026

Dear Yonghui Han:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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.

510(k) Number *(if known)*
K253686

Device Name
True Definition DL

Indications for Use *(Describe)*
True Definition DL is a deep learning based CT reconstruction method intended for high contrast spatial resolution enhancement for bone and lung imaging. True Definition DL 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.

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K253686

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: February 17, 2026

Submitter: GE Medical Systems, LLC
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Device Trade Name: True Definition DL
Device Classification Class II
Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name: Deep Learning Image Reconstruction
Manufacturer: GE Medical Systems, LLC
510(k) Number: K213999
Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Computed Tomography (CT) is an indispensable imaging modality in clinical diagnostics due to its ability to provide detailed cross-sectional images of anatomical structures. However, achieving high spatial resolution remains a persistent challenge, particularly in applications requiring the visualization of fine structural details such as in inner auditory canal imaging, vascular studies, lung imaging, and bone microarchitecture analysis. Reconstruction techniques that attempt to boost spatial resolution typically also would amplify the noise which often result in tradeoffs to be made between resolution and noise.

As part of the continuous innovation to solve the above challenges in CT imaging, GEHC developed a deep learning-based CT reconstruction algorithm specifically designed for high contrast lung and bone imaging, which is the subject of this premarket notification. This reconstruction algorithm, marketed under the name **True Definition DL (TDDL),** is an additional user-selectable recon option specifically designed for lung and bone imaging. It aims to enhance spatial resolution for both in-plane and cross-plane directions. This algorithm is incorporated into the reconstruction chain of the Revolution CT /Apex Family CT systems including Revolution CT/Revolution CT ES, Revolution Apex Elite, Revolution Apex Plus, Revolution Apex Select all cleared under (K213715) and Revolution Vibe (K250941).

True Definition DL offers three strengths that the user can choose depending on enhancement preferences. The benefits provided by this enhancement include improved spatial resolution measured by MTF.

Intended Use

True Definition DL is a deep learning based CT reconstruction method intended for high contrast spatial resolution enhancement.

Indications for Use

True Definition DL is a deep learning based CT reconstruction method intended for high contrast spatial resolution enhancement for bone and lung imaging. True Definition DL may be used for patients of all ages.

Technological Characteristics

Since the True Definition DL is a recon option for the Revolution CT/Apex system, it utilizes the same hardware and software platform for reconstruction. The table below summarizes the substantive feature/technological differences between the predicate device, and the proposed device. The changes described below do not change the fundamental technology of the predicate device or host system and do not raise any new questions of safety and effectiveness.

Specification	Predicate Device Deep Learning Image Reconstruction (K213999)	Proposed Device True Definition DL
Patient Population	Patients of all ages	Same
Reconstruction Matrix	512 x 512 1024 x 1024	1024 x 1024
Anatomies	Head, Body (including bone and lung), Cardiac	Bone and lung
Hardware	DLIR is a recon option implemented on the operator console for Revolution Apex systems.	Same
Clinical workflow	Built into routine clinical workflow with 3 strengths to select from (Low, Medium, High)	Same

Determination of Substantial Equivalence

True Definition DL has successfully completed the design control testing per GE HealthCare's quality system. No additional hazards were identified, and no unexpected test results were observed. True Definition DL was designed under GE HealthCare's QMS per the Quality System Regulations of 21CFR 820 and ISO 13485. GEHC believes that the successfully completed design verification & validation, as well as the extensive bench testing is sufficient for FDA's substantial equivalence determination.

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

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
    - Code Review
    - Software Unit Implementation
    - Software Integrations and Integration Testing
- System Testing
    - Safety Testing (Verification)
    - Image Performance Testing (Verification)
    - Simulating Use Testing (Validation)
- Software Release

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device.

Summary of Non-Clinical Testing

A range of bench testing on phantoms was performed to measure the performance of True Definition DL. The tests include well established test methods using industry-standard IQ metrics. The test data demonstrated acceptable overall image quality and substantially equivalent performance of True Definition DL to the predicate measured on the Revolution CT/Apex scanner's traditional metrics.

The result of the bench testing showed that True Definition DL improves the in-plane and cross-plane resolution for body (lung and bone) scans as well as bony structures in the head acquired from Revolution CT/Apex without significantly increasing the image noise, in comparison with a sharper resolution kernel.

To evaluate the algorithm robustness of the True Definition DL algorithm, GEHC conducted qualitative and quantitative test utilizing the entire image reconstruction pipeline. The testing also included assessment of hallucination risks and their mitigations with the results indicating that True Definition DL consistently enhanced anatomical edges without introducing spurious structures, preserved noise texture under realistic dose conditions, and maintained strong correlation with input and target images across all frequency bands.

Summary of Clinical Testing

The clinical testing was carried out in the form of a reader study of sample clinical data processed using True Definition DL software. The images were evaluated by US board-certified radiologists.

The result of this reader study validated that True Definition DL provides diagnostic value by improving high contrast spatial resolution in routine bone (including inner ears and spines) and lung exams and improves confidence in the assessment of high contrast structures in in these types of images.

In addition, the readers confirmed that the images enhanced by the subject device do not present algorithm-induced artifacts or enhancements not supported by underlying anatomies.

Substantial Equivalence

True Definition DL was developed under GEHC's quality system. Design verification, along with bench testing and the clinical reader study provided in this submission demonstrates that True Definition DL is substantially equivalent to the predicate device. Verification & Validation testing and risk management processes did not raise any new questions of safety or effectiveness, or unexpected results, or adverse effects stemming from the changes. GE HealthCare believes that True Definition DL is substantially equivalent to the predicate, hence it is safe and effective for its intended use.