April 11, 2024

GE Healthcare Japan Corporation
% Laura Turner
Regulatory Affairs Manager, Premium CT
7-127, Asahigaoka, 4-chome
HINO-SHI, TOKYO 191-8503
JAPAN

Re: K233698
Trade/Device Name: True Enhance DL
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 17, 2023
Received: November 17, 2023

Dear Laura Turner:

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.

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
Devices and Electronic Products
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.

510(k) Number *(if known)*
K233698

Device Name
True Enhance DL

Indications for Use *(Describe)*
True Enhance DL is a deep learning-based image processing method trained to estimate monochromatic, 50 keV GSI images. The algorithm is intended to improve the contrast of 120 kVp, single energy images of the body.

This device is intended to provide non-quantitative, adjunct information and should not be interpreted without the original 120 kVp image.

True Enhance 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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GE HealthCare
510(k) Premarket Notification Submission
True Enhance DL

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 807.92:

Date:	April 10, 2024
Submitter:	GE Healthcare Japan Corporation 7-127, Asahigaoka, 4-chome Hino-shi, Tokyo, 191-8503, Japan
Primary Contact:	Laura Turner Regulatory Affairs Manager Phone: 1-262-200-1044 Email: laura.turner@ge.com
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Subject Device Name:	True Enhance DL
Device Classification	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name:	Revolution Ascend
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K213938 cleared on February 4, 2022
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

True Enhance DL is a deep learning-based image processing method intended for contrast enhanced images of the body obtained using the Revolution Ascend Family (K213938), which consists of multiple commercial configurations: Revolution Ascend Elite, Revolution Ascend Plus, and Revolution Ascend Select. True Enhance DL is intended to post-process single energy, 120 kVp images to output non-quantitative, adjunctive information with better contrast than single energy input data.

True Enhance DL brings four deep leaning models that the user can choose depending on different contrast enhancement phases. These four models are CT Angiography, Arterial, Portal/Venous, and Delayed True Enhance DL.

True Enhance DL is not intended to replace hardware based Monochromatic Imaging by Gemstone Spectral Imaging (GSI) technology or replicate GSI dual energy acquisitions. The device was trained to estimate monochromatic, 50 keV GSI images, and only enhances images from 120 kVp acquisitions on non-GSI Revolution Ascend systems.

Intended Use

True Enhance DL is a deep learning-based image processing method intended for contrast enhancement of single energy images.

Indications for Use

True Enhance DL is a deep learning-based image processing method trained to estimate monochromatic, 50 keV GSI images. The algorithm is intended to improve the contrast of 120 kVp, single energy images of the body.

This device is intended to provide non-quantitative, adjunct information and should not be interpreted without the original 120 kVp image.

True Enhance DL may be used for patients of all ages.

Technological Characteristics

Since the True Enhance DL option is deployed within Revolution Ascend acquisition and processing software, it utilizes the same hardware and software platform to reconstruct images that achieve contrast enhancement from single kVp images. Use of True Enhance DL does not require that the acquisition parameters used for the 120 kVp input images to be altered. The table below summarizes the substantive feature / technological differences between the predicate device and the proposed device:

Specification	**Predicate Device** **Revolution Ascend** **(K213938)**	**Proposed Device** **True Enhance DL** **on Revolution Ascend**
Patient Population	Patients of all ages	Same

Specification	**Predicate Device** **Revolution Ascend** **(K213938)**	**Proposed Device** **True Enhance DL** **on Revolution Ascend**
Clinical Workflow	The Revolution Ascend User Interface allows for modifications of image reconstruction settings (FBP, ASiR-V, and other parameters) based on users desired image display and workflow set up.	Same
Supported kVps	80, 100, 120, 140	120
Supported Recon Kernels	- Standard - Soft - Detail - Bone, Bone plus - Chest - Lung - Ultra - Edge, Edge plus	- Standard - Soft - Detail
Image Reconstruction	- Filtered back Projection - ASiR-V - Deep Learning Image Reconstruction, DLIR (K230807)	- Filtered back Projection - ASiR-V

The different technological characteristics do not raise different or new question of safety and effectiveness, and that the device is as safe and effective the legally marketed predicate.

Determination of Substantial Equivalence

True Enhance DL has successfully completed the design control testing per GE's quality system. No additional hazards were identified, and no unexpected test results were observed. True Enhance DL was designed under 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 and clinical testing is sufficient to demonstrate the device's substantial equivalence to the predicate.

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

GE believes True Enhance DL on Revolution Ascend is of comparable type and substantially equivalent to our currently marketed system Revolution Ascend (K213938). The testing and results did not raise different questions of safety and effectiveness than associated with predicate device.

Summary of Non-Clinical Testing

The verification and validation testing have been successfully completed as required by design control procedures under GE Healthcare's quality system. This includes risk management, software verification and validation testing as well as image quality performance evaluation using well established metrics and methods. IQ evaluation include:

- General IQ Performance testing of metrics identified in IEC 61223-3-5 Ed. 2 to study the overall performance in a standardized and referenceable manner.
- IQ performance test comparison using standard IQ, QA, and anthropomorphic phantoms for representative conditions to characterize image quality of True Enhance DL on Revolution Ascend, and predicate Revolution Ascend

All the testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device.

Clinical Testing

The clinical testing was carried out in the form of a reader study of sample clinical data. The reader study used retrospectively collected representative clinical cases, including cases with disease/pathology, that were processed using True Enhance DL software. The images generated from the subject device were read by four board certified radiologists. The four radiologists each provided a comparative assessment of image quality related to diagnostic use. Additionally, the readers were asked to rate the contrast enhancement in the True Enhance DL series vs the native image series.

Additional representative clinical cases and anthropomorphic phantom cases from a GSI system generating both single energy 120 kVp and 50 keV monochromatic images were evaluated for CT

number in various anatomical regions to study image characteristics for different materials of the device output compared to 50 keV and 120 kVp reference images.

The result of this reader study and head-to-head material comparison validated that True Enhance DL software provides additional benefit by improving contrast in the True Enhance output when compared to the original 120 kVp single energy images.

Substantial Equivalence

The changes associated with True Enhance DL do not create a new Intended Use and represent technological characteristics that produce images that have demonstrated adequate image quality and contrast improvement relative to the 120 kVp input.

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, the additional engineering bench testing, and the clinical testing demonstrates that True Enhance DL is substantially equivalent to and as safe and as effective for its Intended Use, as the legally marketed predicate device.