September 8, 2025

NeuroLogica Corporation
℅ Ninad Gujar
Vice President
14 Electronics Avenue
DANVERS, MA 01923

Re: K250928
Trade/Device Name: OmniTom Elite with PCD
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 27, 2025
Received: July 7, 2025

Dear Ninad Gujar:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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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)*
K250928

Device Name
OmniTom Elite with PCD

Indications for Use *(Describe)*
The OmniTom Elite with PCD computed tomography (CT) system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40 cm aperture, primarily head and neck.

The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast. The PCD CT system has multi-energy CT functionality with spectral capability for material decomposition and virtual monoenergetic images (VMI).

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

K250928

Date Prepared: March 27, 2025

Submitter
NeuroLogica Corp., a subsidiary of Samsung Electronics Co., Ltd
14 Electronics Avenue, Danvers, MA 01923

Establishment Registration
3004938766

Manufacturing Site
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Device Name:

Trade Name:	OmniTom Elite with PCD
Device Model:	NL5100
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Predicate Device:

510(k):	K233767
Trade Name:	OmniTom Elite
Device Model:	NL5000
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Device Description:
The subject OmniTom Elite with PCD Computed Tomography (CT) system provides the same functionality as the previous version of the device, OmniTom Elite (K233767). Both computed tomography systems are identical in terms of the high resolution, 16 row, 40 cm bore, and 30 cm field of view. The lightweight translating gantry consists of a rotating disk with a solid-state x-ray generator, collimator, control computer, communications link, power slip-ring, data acquisition system, reconstruction computer, power system, brushless DC servo drive system (disk rotation) and an internal drive system (translation). The power system consists of batteries which provide system power while unplugged from the charging outlet. The system has the necessary safety features such as the emergency stop switch, x-ray indicators, interlocks, patient alignment laser and 110% x-ray timer. The gantry has omni-directional wheels that allow for robust diagonal, lateral, and rotational 360-degree movement and electrical drive system so the system can be moved easily to different locations.

OmniTom Elite system with photon counting detector (PCD) provides the ability to capture CT data in multiple energy bands that can provide information on material composition of different tissues and contrast media. The multiple sets of CT data are acquired at the same time with configurable energy thresholds without any cross talk between images.

Indications for Use:
The OmniTom Elite with PCD computed tomography (CT) system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40 cm aperture, primarily head and neck.

The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast. The PCD CT system has multi-energy CT functionality with spectral capability for material decomposition and virtual monoenergetic images (VMI).

Comparison of Technological Characteristics with the Predicate Device:
We modified the cleared OmniTom Elite (K233767) within our design controls to include technology improvements that expand the intended use for pediatric scanning.

The indications for use between the subject device and the predicate device (K233767) only vary slightly, in that the subject device includes both adult and pediatric imaging. The subject device still contains the same technology and basic functionality as the predicate device (K233767), and therefore, safety and efficacy are not of a concern. Please find both the subject and predicate indications for use below.

OmniTom Elite with PCD (Subject Device)	OmniTom Elite with EID and PCD (Predicate – K233767)
The OmniTom Elite with PCD computed tomography (CT) system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40 cm aperture, primarily head and neck. The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast. The PCD CT system has multi-energy CT functionality with spectral capability for material decomposition and virtual monoenergetic images (VMI).	The OmniTom Elite computed tomography (CT) system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40cm aperture, primarily head and neck. The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast. OmniTom Elite with photon counting detectors (PCD) configuration has multi-energy CT functionality with spectral capability for material decomposition and virtual monoenergetic images (VMI). OmniTom Elite with PCD is only supported for adult axial imaging for head and neck.

The OmniTom Elite with PCD (subject device) and OmniTom Elite with PCD configuration (K233767) are both CT systems used for similar imaging purposes. In the proposed device, for easy of identification and manufacturability, we have created a separate model number for it – NL5100.

OmniTom Elite with PCD (NL5100) for its intended use, is of comparable type in design, material, functionality, and technology and is substantially equivalent to the cleared predicate device – OmniTom Elite with the PCD configuration (NL5000).

<u>Similarities</u>

- Design: The OmniTom Elite with PCD is identical in design characteristics to its previous version and shares all the control system designs and features of the cleared predicate device.

- Components: The OmniTom Elite with PCD uses similar components as the predicate device (OmniTom Elite with PCD configuration) such as x-ray generator, collimator, slip ring and power system.

- Detector coverage is the same:
  - 16 x 0.707 mm for PCD (standard resolution)
  - 26 X 0.424 mm for PCD (high resolution)
  - 80 X 0.141 (ultra high resolution)

Differences

The following differences exist between the subject device (OmniTom Elite with PCD) and its previously cleared version, predicate device (K233767).

- The subject device (OmniTom Elite with PCD) software is enhanced to expand the intended use for the ability to scan pediatric patients. No other changes are included in this submission.

- The PCD CT system allows scanning between 80kV to 120kV with scan currents between 5 and 40 mA.

General Safety and Effectiveness:

All components of the subject OmniTom Elite CT system that are subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR §1020.30 and §1020.33 are certified to meet those requirements. To minimize electrical, mechanical and radiation hazards, NeuroLogica adheres to recognized and established industry practices.

OmniTom Elite CT system is designed and manufactured to comply with the FDA Quality System Regulations (21 CFR part 820) and ISO 13485:2016 requirements. The device is in conformance with all applicable parts of the following FDA recognized consensus standards:

FDA Recognition Number	Standard	Description	Version
19-46	AAMI / ANSI ES 60601-1	Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance	2021

FDA Recognition Number	Standard	Description	Version
19-36	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility. Requirements and Tests	2020
12-336	IEC 60601-1-3	Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment	2021
5-132	IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	2020
12-302	IEC 60601-2-44	Medical Electrical Equipment- Part 2-44: Particular Requirements for Basic Safety and Essential Performance of X-Ray Equipment for Computed Tomography	2016
12-273	IEC 60825-1	Safety Of Laser Products - Part 1: Equipment Classification, And Requirements	2007
5-125	ISO 14971	Medical Devices - Application Of Risk Management To Medical Devices	2019

FDA Recognition Number	Standard	Description	Version
13-79	IEC 62304	Medical Device Software - Software Life Cycle Processes	2015
5-134	ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	2016
2-258	ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
2-245	ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
2-296	ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2021
13-122	IEC 81001-5-1	Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle	2021
19-48	ANSI/USEMCSC C63.27	American National Standard for Evaluation of Wireless Coexistence	2021

FDA Recognition Number	Standard	Description	Version
12-325	NEMA XR 25	Computed Tomography Dose Check	2019
NR	NEMA XR 26	Access Controls for Computer Tomography: Identification, Interlocks, and Logs	2012
12-330	NEMA XR 28	Supplemental Requirements for User Information and System Function Related to Dose in CT	2018
NR	NEMA XR 29	Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management	2013
12-363	NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM) Set	2024
21 CFR subchapter J § 1020.30	FDA	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic x-ray systems and their major components	2023
21 CFR subchapter J § 1020.33	FDA	Performance Standards for Ionizing Radiation Emitting Products: Computed tomography (CT) equipment	2023

The OmniTom Elite was designed in accordance with the following FDA Guidance documents:

- *Content of Premarket Submissions for Device Software Functions, June 2023*
- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023*
- *Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions, September 2023*
- *Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors, August 2023*
- *Electronic Submission Template for Medical Device 510(k) Submissions, October 2023*
- *Medical Device Accessories – Describing Accessories and Classification Pathways, December 2017*
- *Computer Software Assurance for Production and Quality System Software, September 2022*
- *Guidance for Postmarket Management of Cybersecurity in Medical Devices, December 2016*
- *Off-The-Shelf Software Use in Medical Devices, August 2023*
- *Guidance for Deciding When to Submit a 510(k) for a Change to an Existing Device, October 2017*
- *Deciding When to Submit a 510(k) for a Software Change to an Existing Device, October 2017*
- *Guidance for Medical X-Ray Imaging Devices Conformance with IEC Standards, May 2019*
- *Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems, September 2003*
- *Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI), July 2021*
- *Premarket Assessment of Pediatric Medical Devices, March 2014*
- *Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017*
- *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], July 28, 2014*
- *Guidance for Industry and FDA Staff: Use of Standards in Substantial Equivalence Determinations, March 12, 2000*
- *Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22; (Laser Notice No. 50), June 2007*
- *Radiofrequency Wireless Technology in Medical Devices, August 2013*
- *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*

In addition to conformance to the above harmonized standards, OmniTom Elite quality assurance activities include the following:

- Risk analysis and mitigation
- Software verification and validation testing
- System verification and validation testing
- Image quality tests
- Testing at unit level

Performance Data:

The risk analysis, verification and validation activities and testing of product safety and EMC / EMI was completed successfully. The differences noted raise no new issues based on all testing performed and establish that specifications for the device have been met. Below a summary has been provided for the testing conducted.

Bench testing

The software contained in the proposed device has been developed & tested in accordance with IEC 62304, and the FDA guidance for *Content of Premarket Submissions for Device Software Functions*. Software is critical to the operation of the OmniTom Elite CT system and a malfunction or design flaw in the software could result in delay in delivery of appropriate medical care. As such, the risk management analysis identified potential hazards which were controlled and mitigated during development of OmniTom Elite. The verification/validation testing ensured substantial equivalence of OmniTom Elite.

Design verification and design validation testing was performed to confirm all design and user requirements were met. The proposed OmniTom Elite with PCD device demonstrated that the new features did not exhibit any negative effects on the requirements in place, as well as they did not exhibit any concerns.

Software verification and software validation testing was executed to confirm all software requirements were met. The proposed OmniTom Elite with PCD device was shown to meet all requirements and to not have any impact on imaging.

The OmniTom Elite underwent Electrical Safety and Electromagnetic Compatibility testing and proved to be in compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-44.

In addition, performance testing was completed successfully to validate the spectral imaging features using pediatric protocols. The phantom containing different concentration of solid iodine, different concentration of calcium, solid water, and human tissue-equivalent inserts was scanned with multiple energy thresholds. The system provides the

same multi-energy applications for pediatric as the adult head utilizing the same basis material pairs, calibration methods, and energy binning for pediatric protocols as it does for adults.

Image quality evaluation

Image quality metrics such as noise, slice thickness, low and high contrast resolution, radiation metrics, and modulation transfer function (MTF) were measured utilizing phantom image quality tests in accordance with the equipment performance standards for diagnostic x-ray systems administered by the FDA. Image quality testing for pediatric protocols was evaluated for MTF, noise power spectrum, CT linearity, slice width, low contrast, noise and uniformity using pediatric-sized phantoms to ensure the results are within our defined measurement tolerance limits.

Imaging metrics successfully demonstrated that the proposed device with PCD has comparable image quality with its previous version, predicate device (K233767) and meets all the image quality criteria that are used for testing.

Phantom based evaluation

Phantom based study was conducted for evaluation of OmniTom Elite with PCD images. This CT images of head for the pediatric phantom included four sections of the midbrain, sinuses and through the neck while the body sections for the pediatric phantom had lung and abdomen. These images were reviewed by independent board-certified practicing radiologists and confirmed diagnostic quality of the images demonstrating the effectiveness of the subject device for clinical scanning.

The scans indicate the ability of the PCD configuration of the OmniTom Elite device to generate diagnostically acceptable images, which are equivalent to those produced by predicate device. The subject device clinical benefits outweigh the risks and as such the device should be considered safe for its intended use and performs like other CT devices currently on the market. The evaluation demonstrates performance of the OmniTom Elite with PCD CT system, when used under the conditions and for the purposes intended.

Conclusion

Both the proposed device (OmniTom Elite with PCD) and the predicate device (K233767) are CT systems that are used for similar CT imaging purposes. The overall design of the CT system and basic functionality that it provides to the end user are the same. The differences in technological characteristics through the additional software features adding pediatric imaging do not raise additional questions and the system demonstrates substantial equivalence.

The results of the performance testing and conformance to the harmonized standards demonstrate that the subject device operates in accordance with specifications and meets user needs and intended use. The proposed OmniTom Elite with PCD CT system performs as well in its intended use as similar CT devices currently on the market.