February 25, 2022

NeuroLogica Corporation, a subsidiary of Samsung Electronics Co., Ltd
℅ Ninad Gujar
Vice President, Regulatory Affairs and Quality Assurance
14 Electronics Avenue
DANVERS MA 01923

Re: K211711
Trade/Device Name: OmniTom Elite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 26, 2022
Received: January 28, 2022

Dear Dr. 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211711

Device Name
OmniTom Elite

Indications for Use *(Describe)*
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) can generate spectral CT images at multiple energy levels. OmniTom Elite with PCD is only supported for adult imaging for anatomy that can be imaged in the 40cm aperture, primarily head and neck.

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

K211711

In accordance with 21 CFR § 807.92, the 510(k) summary includes information on safety and effectiveness.

Date Prepared: June 2, 2021

Submitter
NeuroLogica Corporation, a subsidiary of Samsung Electronics Co., Ltd
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Establishment Registration
3004938766

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Device Name:

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)

Predicate Device:

510(k):	K202526
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 Computed Tomography (CT) system provides the same functionality as the previous version of the device, OmniTom Elite (K202526). We have included some other design changes to make the system more robust and reliable. 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.

We have added the ability to upgrade the OmniTom Elite system with photon counting detector (PCD). OmniTom Elite with PCD is the same system as the predicate device OmniTom Elite energy integrating detector (EID) with the only difference being the detector array system, instead of the current gadolinium oxysulfide EID, it has a cadmium telluride based PCD.

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. OmniTom Elite with PCD has the capacity to more than double the EID detector spatial resolution.

Indications for Use:

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) can generate spectral CT images at multiple energy levels. OmniTom Elite with PCD is only supported for adult imaging for anatomy that can be imaged in the 40cm aperture, primarily head and neck.

Comparison of Technological Characteristics with the Predicate Device:
We modified the cleared OmniTom Elite (K202526) within our design controls to include technology improvements that include hardware features for enhancing movement control, manufacturability, and serviceability of the CT system.

The indications for use between the subject device (K211711) and the predicate device (K202526) only vary slightly, in that the subject device offers the optional addition of the photon counting detector. The subject device (K211711) still contains the same basic functionality as the predicate device (K202526), and therefore, is one of many reasons why safety and efficacy are not of a concern. Please find both the subject and predicate indications for use below.

OmniTom Elite with PCD (Subject – K211711)	**OmniTom Elite with EID (Predicate – K202526)**
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) can generate spectral CT images at multiple energy levels. OmniTom Elite with PCD is only supported for adult imaging for anatomy that can be imaged in the 40cm aperture, primarily head and neck.	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.

For the optional upgrade of the photon counting detector (PCD), updates were made to the data acquisition system for PCD. OmniTom Elite with the optional PCD kit can replace the existing EID based data acquisition system, and 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 (K202526).

Similarities

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

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

- Software: The OmniTom Elite, with the exclusion of PCD kit, uses the same software as the predicate (K202526). Refer to the differences listed below for software differences with PCD.

Differences

The following differences exist between the subject device (OmniTom Elite) and its previously cleared version, predicate device (K202526).

- Movement controls: The addition of a drive camera (SmartDrive) and new transport wheels (OmniWheels) for simpler navigation; the drive bar mechanism was enhanced for durability, easier manufacturability and ease of operator overall transportation of device.

- Noise reduction algorithms: The algorithms are sinogram and image-based reconstruction algorithms designed for the purpose of allowing low-dose scanning by decreasing the noise level in the reconstructed images. The feature is used during post reconstruction and recommended for pediatric scanning and for scanning large patients. The noise algorithm has been enhanced to allow for the use of the three output energy levels.

- Addition of optional PCD upgrade; these changes/features are only included if the PCD kit is chosen by end user:

    - Update to the detector material to CdTe (cadmium telluride) and the data acquisition system (DAS).
    - Minor software differences to allow for the generation of the multi-energy levels derived from the primary scan.
    - The ability to contain configurable energies prior to starting scans
    - No crosstalk noticed between images

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
19-4	AAMI / ANSI ES 60601-1	Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety And Essential Performance	2012
19-8	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	2014
12-269	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	2013
5-89	IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Usability	2013

FDA Recognition Number	Standard	Description	Version
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
13-79	IEC 62304	Medical Device Software - Software Life Cycle Processes	2015
5-117	ISO 15223-1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - 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

FDA Recognition Number	Standard	Description	Version
2-174	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010
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
12-300	NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM) Set	2016
21 CFR subchapter J § 1020.30	FDA	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic x-ray systems and their major components	2020

FDA Recognition Number	Standard	Description	Version
21 CFR subchapter J § 1020.33	FDA	Performance Standards for Ionizing Radiation Emitting Products: Computed tomography (CT) equipment	2020

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

- *Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2018*
- *Off-The-Shelf Software Use in Medical Devices, September 2019*
- *Guidance for Medical X-Ray Imaging Devices Conformance with IEC Standards, May 2019*
- *Guidance for Industry and FDA Staff: Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017*
- *Guidance for Industry and FDA Staff: Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22, June 24, 2007*
- *Radiofrequency Wireless Technology in Medical Devices, August 14, 2013*

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 of safety or effectiveness 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 Software Contained in Medical Devices*. 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 the safety and effectiveness of OmniTom Elite.

Design verification and design validation testing was performed to confirm all design and user requirements were met. The proposed OmniTom Elite 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 that may impact safety and effectiveness.

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

The OmniTom Elite with PCD 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.

Image quality evaluation

Image quality metrics such as noise, slice thickness, low and high contrast resolution, radiation metrics, and modulation transfer function were measured utilizing phantom image quality tests in accordance with the equipment performance standards for diagnostic x-ray systems administered by the FDA. Imaging metrics successfully demonstrated that the proposed device with PCD has comparable image quality with its previous version, predicate device (K202526) that had EID and meets all the image quality criteria that are used for testing.

In addition, PCD capabilities were tested to demonstrate properties of PCD in count and multi-energy mode. For imaging purposes, the pixels were binned to match the predicate device detector geometry. Imaging metrics demonstrated stability of the detector, analysis of the count rate and limited pileup loss at low dose scanning.

Clinical evaluation

Comparative study was conducted under an IRB for comparison between OmniTom Elite with PCD and OmniTom Elite with EID images. The section on technological characteristics detailed that the subject and predicate device are mechanically identical. They have the same geometry, i.e., gantry size and weight and the same x-ray tube which guarantees that both scanners deliver the same photon number for the same exposure. The only difference is the DAS.

Volunteers underwent scanning to aid in generation of comparative images. The comparative study involved scanning the same subject using both the EID and the PCD CT systems at the same anatomical sections or as closely as possible. Three locations were selected for the comparative study: The sinuses, the mid brain, and the top of the skull. These images were reviewed by two independent board-certified radiologists and confirmed diagnostic quality of the images demonstrating the effectiveness of the subject device for clinical scanning. In addition, full head scan was conducted to demonstrate the ability of the PCD system in doing complete clinical scanning as needed.

Conclusion

Both the proposed device (OmniTom Elite) with the optional PCD upgrade and the predicate device with EID (K202526) 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 do not raise different questions of safety and effectiveness. The improvements in movement performance were implemented to solely allow the operator to transport the device with ease. The PCD optional kit provides a multi-energy CT functionality with spectral capability. 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 CT system performs as well in its intended use as similar CT devices currently on the market.