DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

NeuroLogica Corporation, a subsidiary of Samsung Electronics Co., Ltd.
% Dr. Ninad Gujar
Director, Regulatory Affairs and Quality Assurance
14 Electronics Avenue
DANVERS MA 01923

August 18, 2017

Re: K171183
Trade/Device Name: OmniTom
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 21, 2017
Received: July 25, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171183

Device Name
OmniTom

Indications for Use *(Describe)*
The NL5000 [OmniTom] 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.

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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510(k) SUMMARY

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92

Date: April 21, 2017

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

Contact:
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Device Name:

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

Predicate Device:

Trade Name:	CereTom
510(k) number:	K051765 cleared 07/14/2005
Manufacturer:	NeuroLogica Corporation, a subsidiary of Samsung Electronics Co., Ltd (same as that of proposed device)
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Reference Device:

Trade Name:	GR40CW Retrofit Kit
510(k) number:	K153401 cleared 12/21/2015
Manufacturer:	Samsung Electronics Co., Ltd
Classification Name:	Solid State X-ray Imager (Flat panel/Digital imager)
Product Code:	MQB

Device Classification: Class II (per 21 CFR 892.1680)

Device Description:
The NL5000 CT System is a high resolution, 16 row, 40 cm bore, and 30 cm field of view x-ray computed tomography system. The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, Gd_2O_2S detector array, 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.

Indications for Use:
The NL5000 [OmniTom] 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.

Comparison of Technological Characteristics with the Predicate Device:

NeuroLogica Corporation believes that the OmniTom system, for its intended use, is of comparable type in design, material, functionality, technology and is substantially equivalent to the cleared predicate device – CereTom (K051765).

<u>Similarities</u>

- Material: The OmniTom uses similar material to CereTom (K051765) such as, x-ray generator, slip ring, rotational bearing, and motion control systems.

- Design: The OmniTom is similar in general design principle to CereTom (K051765). Specifically, it shares most of the control system designs and features of the CereTom.

<u>Differences</u>

- Detector Material: The scintillation properties of the detector material Gadolinium Oxysulfide used in OmniTom CT system are more promising than the detector material Solid State CdWo4 used in the CereTom system (predicate device

K051765). This material has already been cleared for use in the reference device GR40CW Retrofit Kit (K153401 cleared 12/21/2015) which is a Solid State X-ray Imager manufactured by Samsung Electronics Co., Ltd.

- Tablet: OmniTom uses a tablet for running CT application software instead of a PC laptop used with CereTom. A tablet is an accompanying part of each OmniTom scanner and is designed to be used as the control unit to operate all respective functions of the system.

- Internal Drive System: CereTom had an accessory drive system which when connected with the scanner allowed mobility while OmniTom has an internal drive system providing easy movement of the scanner.

- Battery: Lithium batteries are used in OmniTom instead of the lead acid batteries in CereTom are designed and tested to IEC 62133 and UN/DOT 38.3 for safety and transportation.

- Automatic Exposure Control: AEC was not offered on the CereTom system at the time of 510(k) clearance (K051765) but introduced as a device modification through a software/firmware upgrade. OmniTom is XR-29 compliant and as such includes four key features of CT equipment that enable optimization or management of radiation dose delivery – dose structured reporting, CT dose check, AEC and pediatric and adult reference protocols. AEC feature has been verified as part of IEC 60601-2-44, clause 203.102.

- Contrast and Bolus Tracking: OmniTom does not control the contrast injection or the delivery of the contrast volume however has the ability for helical and dynamic scanning. For example, bolus tracking is used for CT Angiography applications.

The internal verification and validation activities and external testing of product safety and EMC / EMI was completed successfully. The differences noted above raise no new issues of safety or effectiveness based on all testing performed.

Model # Name	**OmniTom (subject of this 510(k))**	**CereTom (predicate device K051765)**
Indications for Use	The NL5000 [OmniTom] system is intended to be used for x-ray computed tomography applications that produce cross sectional images for anatomy that can be imaged in the 40 cm aperture, primarily head and neck. The OmniTom 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 NL3000 [CereTom] is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 32cm aperture.
Aperture (cm)	40	32
Image Field Of View (cm)	30	25
Detector Material	Gadolinium Oxysulfide	Solid State CdWO4
Detector coverage (mm)	16 x 0.625	8 x 1.25
Slice Configurations	16	8
Spatial Resolution MTF at 0% (lp/cm)	Soft tissue kernel: 6.0 lp/cm High resolution kernel: 14.0 lp/cm	Soft tissue kernel: 7.0 lp/cm High resolution kernel: 15.0 lp/cm

Model # Name	**OmniTom (subject of this 510(k))**	**CereTom (predicate device K051765)**
X-ray Tube Type	Grounded/Fixed Anode/Monoblock	Grounded/Fixed Anode/Monoblock
Heat Storage (MHU)	0.72	0.45
Cooling	Water-Glycol	Air cooled
Tube Current (mA)	5 - 45	1 - 7
Tube Voltage Range (kV)	80, 100, 120	100, 120, 140
Rotation time (s)	1 , 2	2, 4, 6
Gantry Weight (lbs)	1700	966
Mobile / Stationary	Mobile	Mobile
Battery / Wall power	Lithium battery	Lead acid battery
Input Voltage	Single phase 90 - 264 VAC/1300 watts peak	Single phase 90-264VAC
Max Input Power (kVA)	5.4 kW	1.3 kW
PACS DICOM 3.1	Yes	Yes
2D Scout Scan	Yes	Yes
Bolus Tracking	Yes	Yes
Axial Scan	Yes	Yes
Helical Scan	Yes	Yes
Dynamic Scan	Yes	Yes

Model # Name	**OmniTom (subject of this 510(k))**	**CereTom (predicate device K051765)**
2D Viewing	Yes	Yes
MPR Viewing	Yes	Yes
3D Viewing	Yes	Yes
Maximum Scan Range (cm)	40	25
Scan Localizer	Laser	Laser
Cardiac/Respiratory Gating	No	No
Patient Table	No	No
Image recon speed max (images per second)	16 images / sec	1 image / sec
X-ray Warning Lights	Yes	Yes
110% X-ray Timer	Yes	Yes
Emergency Stop	Yes	Yes
Operator X-ray On Switch	Yes	Yes
Quality Test Phantom	Yes	Yes
Quality Test Report	Yes	Yes
X-ray Filter	Bowtie	Bowtie
Administrator Privileges	Yes	Yes
Dose Display	Yes	Yes
Dose Report / Audit	Yes	Yes

Model # Name	OmniTom (subject of this 510(k))	CereTom (predicate device K051765)
Protocol Override Protection	Yes	Yes
Dose Check	Yes	Yes
Pediatric Protocols	Yes By Age/weight	Yes By Age/weight
Automatic Exposure Control	Yes	No
Biocompatibility	N/A	N/A
Sterility	N/A	N/A
Chemical Safety	N/A	N/A
EM Emissions	ETL Testing	ETL Testing
Electrical Safety (IEC 60601-1)	ETL Testing	ETL Testing
Mechanical Safety (IEC 60601-1)	ETL Testing	ETL Testing
Where Used	(Mobile) Radiology, ICU, ED, OR, Clinic, Office	(Mobile) Radiology, ICU, ED, OR, Clinic, Office
Anatomical Site	Head and Neck	Head and Neck

General Safety and Effectiveness Concerns:

All components of the OmniTom 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 CT system is designed and manufactured to comply with the FDA Quality System Regulations and ISO 13485 requirements. The device is in conformance with all applicable parts of the following FDA Recognized Consensus Standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility. Requirements and Test

- 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

- 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

- NEMA XR 25: Computed Tomography Dose Check

- NEMA XR 29: Standard Attributes on CT Equipment Related to Dose Optimization and Management

- ISO 14971 Medical devices - Application of risk management to medical devices

In addition to conformance to the above harmonized standards, OmniTom 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

FDA Guidance documents specifically related to premarket submissions like management of cybersecurity in medical devices, software contained in medical devices, pediatric medical devices and conformance with IEC standards were utilized during the development of OmniTom device.

Software is critical to the operation of the OmniTom CT scanner 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. The verification/validation testing ensured the safety and effectiveness of OmniTom.

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. Subsequent testing for artifact analyses associated with typical clinical techniques demonstrated the performance of the CT system in the presence of implants.

Phantom image evaluations were performed for pediatric scans along with clinical images for adult brain exams. The data provided clinical demonstration of the operation of the device and the images reviewed by a board-certified radiologist were of diagnostic quality.

The OmniTom scanner successfully demonstrated that it has comparable image quality as the predicate device CereTom (K051765) and meets all the image quality criteria that are used for testing the CereTom.

Conclusion

Based upon the above considerations, NeuroLogica Corporation, subsidiary of Samsung Electronics, believes that the OmniTom CT system is of comparable type in design, functionality, and technology and is, for its intended use, substantially equivalent to the predicate device CereTom (K051765).

The proposed modifications do not result in any new safety or effectiveness concerns. The OmniTom CT system performs as well in its intended use as similar devices currently on the market.