DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 14, 2017

NeuroLogica Corporation, a Subsidiary of Samsung Electronics
Ninad Gujar
Director, Regulatory Affairs & Quality Assurance
14 Electronics Avenue
Danvers, Massachusetts 01923

Re: K170238
Trade/Device Name: BodyTom Elite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 8, 2017
Received: May 17, 2017

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 (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,

For

Robert A. 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)*

K170238

Device Name
BodyTom Elite

Indications for Use *(Describe)*

The NL4000 BodyTom Elite CT system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture.

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.

BodyTom Elite CT system can be used for low dose lung cancer screening. The screening must be performed in compliance with the approved and established protocols as defined by professional medical societies.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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

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

Date: January 24, 2017

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

Contact:
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Director, Regulatory Affairs & Quality Assurance
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Device Name:

Trade Name:	BodyTom Elite
Device Model:	NL4000
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Predicate Device:

Trade Name:	BodyTom
510(k) number:	K102677 cleared 03/24/2011
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:	Philips Multislice CT System with Low Dose CT Lung Cancer Screening
510(k) number:	K153444 cleared 04/08/2016
Manufacturer:	Philips Medical Systems (Cleveland), Inc
Classification Name:	Computed Tomography X-ray System

Product Code: JAK
Device Classification: Class II (per 21 CFR § 892.1750)

Device Description:
The BodyTom Elite is an improved version of BodyTom computed tomography (CT) system providing enhanced functionality. It still has the same high resolution, multi row, 85cm bore and 60cm field of view. The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, solid state 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 stepper 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 retractable rotating caster wheels and electrical drive system so the system can be moved easily to different locations.

Indications for Use:
The BodyTom Elite CT system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture.

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.

BodyTom Elite CT system can be used for low dose lung cancer screening. The screening must be performed in compliance with the approved and established protocols as defined by professional medical societies.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Substantial Equivalence:
NeuroLogica has modified the cleared BodyTom (K102677) within our design controls to include few technology improvements and features like automatic exposure control, metal artifact reduction, low dose lung cancer screen protocol, wireless access point and tilt sensor for floor qualification. Both the predicate and reference devices have the same intended use as the new device. The low dose CT lung cancer screening protocol has been previously cleared on Philips Multislice CT System with Low Dose CT Lung Cancer Screening (K153444) and BodyTom Elite has a similar clinical protocol.

BodyTom Elite incorporates the same fundamental operating principles as the existing marketed products BodyTom (K102677) and Philips Multislice CT systems (K153444).

NeuroLogica Corporation believes that the BodyTom Elite system, for its intended use, is of comparable type in design, material, functionality, technology and is substantially equivalent to the cleared predicate device – BodyTom (K102677).

- Design: The BodyTom Elite is similar in general design principle to both the above listed CT systems. Specifically, it shares all of the control system designs and features of the BodyTom.

- Material: The BodyTom Elite uses the same material as the predicate device (BodyTom) such as solid state detectors, x-ray generator, slip ring, data acquisition ICs, rotational bearing, and motion control systems.

The following technology differences exist between the subject device (BodyTom Elite) and the previously cleared predicate device (BodyTom).

- Automatic exposure control: Automatic exposure control (AEC) was not offered on the predicate device (K102677) at the time of 510(k) clearance but introduced as a device modification through a software/firmware upgrade. AEC feature has been verified as part of IEC 60601-2-44, clause 203.102 in BodyTom Elite similar to the predicate device.

- Low dose lung scanning protocol: No hardware design changes were required for this feature but specific clinical protocols were generated based on the AAPM guidelines and published clinical literature.

- Metal artifact reduction: The streak artifacts around metal leads and screws can be reduced using metal artifact reduction. This has been tested in the CT system and validated internally.

- Tilt sensor for floor qualification: The tilt sensor measures the flatness of the scan floor. The tilt sensor function measures the variation of the scan trajectory which is used to determine the flatness of the scan floor. The tilt sensor has been tested on multiple floors as part the validation protocol and does not raise any new safety or effectiveness concerns.

- Wireless access point: The wireless access point provides better security and stability of wireless communication in BodyTom Elite by creating a standalone

wireless network for the scanner compared to the existing Ad-Hoc wireless environment. Physically, the wireless access point is part of the workstation and has undergone EMC testing. This wireless access point has been tested internally for connectivity.

- Contrast capability: BodyTom (predicate device) had the ability for axial, helical and dynamic scanning for CT Angiography (CTA) and CT Perfusion (CTP) applications, including bolus tracking. The contrast imaging capability is added to the expanded indications for BodyTom Elite (subject device) and additional performance testing data is provided for this purpose. The BodyTom Elite scanner does not control the dose, rate or route of administration for the contrast agent.

- NEMA XR-29: BodyTom Elite 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.

The differences noted above raise no new issues of safety or effectiveness based on all testing performed. The below table highlights comparison of technological characteristics with the predicate device.

Specification	**BodyTom Elite (subject of this 510(k))**	**BodyTom (predicate device K102677)**
Indications for Use	The NL4000 BodyTom 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 85cm aperture. The BodyTom system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based	The NL4000 BodyTom is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture.

Specification	BodyTom Elite (subject of this 510(k))	BodyTom (predicate device K102677)
	upon weight and age. The CT images can be obtained either with or without contrast. BodyTom CT system can be used for low dose lung cancer screening.	
Aperture (cm)	85	85
Image Field Of View (mm)	60	60
Detector Material	Solid State CdWO4	Solid State CdWO4
Detector Coverage (mm)	40	40
Slice Configurations	32	32
Spatial Resolution MTF at 0% (lp/cm)	17.5	17.5
X-ray Tube Type	Rotating Anode	Rotating Anode
Heat Storage (MHU)	3.5	3.5
Cooling	Oil to Air	Oil to Air
Tube Current (mA)	10 to 300	10 to 300
Tube Voltage Range (kV)	80 to 140	80 to 140
Maximum Rotation Speed (s)	1.0	1.0
Gantry Weight (kg)	1200	1200

Specification	BodyTom Elite (subject of this 510(k))	BodyTom (predicate device K102677)
Mobile / Stationary	Mobile	Mobile
Battery / Wall power	Battery	Battery
Input Voltage	Single phase 110-240 volts	Single phase 110-240 volts
Max Input Power (kVA)	3.6 kW	3.6 kW
PACS DICOM 3.0	Yes	Yes
2D Scout Scan	Yes	Yes
Bolus Tracking	Yes	Yes
Axial Scan	Yes	Yes
Helical Scan	Yes	Yes
Dynamic Scan	Yes	Yes
2D Viewing	Yes	Yes
MPR Viewing	Yes	Yes
3D Viewing	Yes	Yes
Gantry Tilt	No	No
Scan Range (cm)	200	200
Scan Localizer	Laser	Laser
Cardiac/Respiratory Gating	No	No
Patient Table	No	No

Specification	BodyTom Elite (subject of this 510(k))	BodyTom (predicate device K102677)
Image recon speed max (images per second)	16	16
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
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

Specification	BodyTom Elite (subject of this 510(k))	BodyTom (predicate device K102677)
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, Fixed Radiology, ICU, ED, OR, Proton Therapy, HDR suite, Clinic, Office	(Mobile) Radiology, ICU, ED, OR, Clinic, Office
Anatomical Site	Whole body	Whole body

Specific image quality metrics were compared between the subject device (BodyTom Elite) and the previously cleared reference device of Philips Multislice CT System with Low Dose CT Lung Cancer Screening (K153444), specifically the Philips Brilliance 16 Family (K012009) was used as the point of comparison. The subject device and the reference device have similar technological characteristics and fundamental operating principles.

The LDCT LCS and MAR protocols have been tested internally and can be used with the filtered back projection reconstruction algorithms for BodyTom Elite.

Intended Use Discussion:
In accordance with FDA guidance for *Guidance for Industry on General/Specific Intended Use* and the presentation *FDA/MITA Meeting on Low Dose CT Lung Cancer Screening*, the modified indication of use does not alter the intended use for the legally marketed predicate and reference devices.

The specific use of low dose CT (LDCT) lung cancer screening (LCS) was evaluated based on the above criteria:

1. LDCT LCS does not introduce new risks not normally associated with the general use of the CT device. The risks are fundamentally the same as those associated with the use of CT.
2. The specific use of LDCT LCS does not impact public health to a significantly greater degree than the general diagnostic use of the CT device.

3. Published literature, clinical trials including the NLST (N Engl J Med 2011; 365:395-409) and governmental review reflect understanding by the medical community that the specific use of LDCT LCS is a subset of the general use of CT rather than a new intended use.
4. The performance used to evaluate general use of CT has not changed and can also be applied to the specific use of LDCT LCS.
5. LDCT LCS does not perform any treatment.
6. No adjunctive products required for LDCT using CT of the target population.
7. No device modifications / design changes were required to the general use of the CT device and specific clinical protocols were generated based on the AAPM guidelines and published clinical literature. The qualified CT system continues to comply with the applicable US and international safety and performance standards such as 21 CFR, Chapter I, Subchapter J – Radiological Health, NEMA, DICOM and IEC standards.

NeuroLogica believes that there is more than sufficient scientific and medical evidence in the published literature and coverage decisions of the safety and effectiveness of LDCT LCS when performed with a pre-defined high risk group, according to a pre-defined screening program that includes dose targets.

Non Clinical testing:
All components of the BodyTom 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.

BodyTom Elite 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 60601-2-28, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

- 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, BodyTom 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

The software contained in the proposed device has been developed & tested in the software development procedure on 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 BodyTom Elite 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 BodyTom Elite. The level of concern for the software is Moderate because a failure, latent flaw, or delayed information could indirectly result in minor injury to the patient. The verification & validation testing ensured the safety and effectiveness of BodyTom Elite.

Image quality metrics such as uniformity, slice width, 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. In addition the beam profile and the noise power spectrum were also measured. The BodyTom Elite scanner successfully demonstrated that it has comparable image quality as the predicate device and meets all the image quality criteria that are used for testing the BodyTom as it passed all QA requirements.

The image quality metrics utilized to test general CT use are also applicable for LDCT LCS. The imaging parameters for the subject device were measured using standard IQ phantom and compared to the IQ results from the reference device. The imaging parameters that were tested includes the CT number linearity, slice thickness, uniformity and noise level, the low-contrast resolution and the high contrast resolution. For LDCT LCS, in order to measure nodules of at least 4 mm in diameter, the important parameters are listed below:

Imaging Parameter	Reason for Inclusion
Modulation Transfer Function (MTF)	The MTF describes the size of the smallest object that can be seen with large difference in CT value, e.g., soft tissue-air, soft tissue-bone and bone-air. In order to detect a 4 mm object the scanner needs to have at least 2mm sampling rate or resolution of at least 5 lp/cm. A resolution of at least 8 lp/cm is recommended.
Slice Thickness	The slice thickness determines the smallest size that can be seen in scan direction. The CT number is averaged over the volume covered by the slice width. The slice need to be wide enough not to have a high noise and thin enough to allow the identification of objects of at least 4.0 mm in diameter. The ACR recommend a slice thickness under 2.5 mm.
CT number (accuracy and uniformity)	The measured CT number will help determine the nature of the nodule.
CT number linearity	The dose does not affect the CT number, since the filter on the tube does not change. The quality of the X-ray beam is the same at high and low dose. As such, the CT linearity should not be affected by low dose scanning.
Image noise	The background noise increases with LDCT LCS which affects the detectability of the lung nodules based on their size. Our low contrast analysis show good detectability as the lung nodules are surrounded by air. CNR results are included in Performance Testing (section 18).

Imaging Parameter	Reason for Inclusion
Noise Power Spectrum (NPS)	Similar to image noise, changes in noise texture may impact lung nodule detection capabilities as the image noise varies within the field of view. The noise will increase with low dose scanning however the NPS is minimally affected.
Contrast to Noise (CNR)	The CNR is important when the background noise is close to the density of the lung nodules. In general, since lung nodules are surrounded by air, the CNR is typically high even for low dose scanning.
Scanner Speed	The ACR recommend a maximum of 15 seconds scan and pitches that varies from 0.7 to 1.5.

Conclusion:

Based upon the above considerations, NeuroLogica Corporation, subsidiary of Samsung Electronics, believes that the BodyTom Elite Computed Tomography System is of comparable type in design, material, functionality, technology and is, for its intended use, substantially equivalent to the previous version and the predicate device: BodyTom (K102677).

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