April 29, 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: K213649
Trade/Device Name: BodyTom 64
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 30, 2022
Received: March 31, 2022

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. 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)*
K213649

Device Name
BodyTom 64

Indications for Use *(Describe)*
The NL4100 BodyTom 64 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 64 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

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

Date Prepared: November 18, 2021

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Device

Trade Name:	BodyTom 64
Device Model:	NL4100
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Predicate Device

Trade Name:	BodyTom Elite (K170238)
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Device Description

The BodyTom 64 is an improved version of the BodyTom Elite (K170238) computed tomography system, providing enhanced functionality. It still has the same high resolution, multi row, 85 cm bore, and 60 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, Gd2O2S 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 retractable rotating caster wheels and electrical drive system so the system can be moved easily to different locations.

The BodyTom 64 x-ray detector has been updated to allow for 64 cross-sectional CT images (slices) of your body to be generated, instead of the 32 images produced by the predicate BodyTom Elite device (K170238).

Intended Use / Indications for Use

The BodyTom 64 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.

The BodyTom 64 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.

Comparison of Technological Characteristics with the Predicate Device

The BodyTom 64, for its intended use, is of comparable type in design, material, functionality, and technology and is substantially equivalent to the cleared predicate device – BodyTom Elite device (K170238).

We modified the cleared BodyTom Elite (K170238) within our design controls to include technology improvements, which includes hardware updates to the Data Acquisition Board (DAS) to accommodate for the 64 cross sectional CT images produced instead of the previous 32 slices provided by the predicate.

The following differences exist between the subject device (BodyTom 64) and the previously cleared predicate device (BodyTom Elite K170238).

- Data Rate: From a rotating component to a stationary component has increased from 1.25 Gb to 4.25 Gb
- Slice Thickness: The slice thickness has decreased from 1.25mm to 0.625mm to provide more detailed images.
- Software:
    - The operating system has been updated to Linux.
    - The workstation computer software has been updated to account for the new slice thickness values.
- Hardware update: The design of the internal hardware of the BodyTom 64 has been updated to accommodate for the 64 image slices offered.
    - The Data Acquisition System (DAS) control board has been updated to accommodate the new data rate.
    - The slip ring has been updated for higher contactless data transfer.
    - Addition of a heat exchanger to the DAS
    - Updated collimator design to accommodate the 64 image slices.
- Accessories: The BodyTom 64 is accompanied by a workstation computer.

The software revision has undergone several updates since the BodyTom Elite (K170238) was cleared. The updates were implemented to enhance the user experience and improve clinical workflow while using the CT system by adding features based on feedback from our current customers, as well as the inclusion of Linux as the operating system. The BodyTom 64 software functions are similar to the predicate BodyTom Elite (K170238) device.

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. Below a summary has been provided for the testing conducted.

Performance Data

- Bench / Image Testing
  - Bench testing was completed to confirm that the enhancements made to the device had no negative impact on the clinical performance of the CT system. An ACR Phantom was used to measure image metrics, such as CT number linearity, image slice thickness, image noise, low contrast resolution and high contrast resolution.
  - The BodyTom 64 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.

- Verification and Validation
  - Design verification and design validation testing was performed to confirm all design and user requirements were met. The proposed BodyTom 64 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 BodyTom 64 device was shown to meet all requirements and to not have any impact on imaging.

General Safety and Effectiveness Concerns:

All components of the subject BodyTom 64 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 64 CT system is designed and manufactured to comply with the FDA Quality System Regulations 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
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
5-117	AAMI / ANSI / ISO 15223-1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	2016
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

FDA Recognition Number	Standard	Description	Version
21 CFR subchapter J § 1020.30	FDA	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic x-ray systems and their major components	2019
21 CFR subchapter J § 1020.33	FDA	Performance Standards for Ionizing Radiation Emitting Products: Computed tomography (CT) equipment	2019

The BodyTom 64 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, BodyTom 64 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 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 BodyTom 64 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 BodyTom 64. The verification/validation testing ensured the safety and effectiveness of BodyTom 64.

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. The BodyTom 64 system successfully demonstrated that it has comparable image quality as the predicate device BodyTom Elite (K170238) and meets all the image quality criteria that are used for testing the BodyTom 64.

Conclusion

Both the proposed device (BodyTom 64) and the predicate device (BodyTom Elite (K170238) are CT systems that are used for pediatric and adult imaging (same intended use). 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 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 BodyTom 64 CT system performs as well in its intended use as similar devices currently on the market.