March 14, 2025

NeuroLogica Corporation, a subsidiary of Samsung
% Ninad Gujar
Vice President
Electronics Co., Ltd.
14 Electronics Avenue
DANVERS, MA 01923

Re: K242811
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: February 7, 2025
Received: February 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 Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242811

Device Name

BodyTom 64

Indications for Use *(Describe)*

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.

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.

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.

K242811

510(k) Summary

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

Date Prepared: September 2, 2024

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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Official Correspondent & **Contact Person**
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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 64 (K213649)
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Reference 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

BodyTom 64 computed tomography (CT) system provides the same functionality as the previous version of the device BodyTom 64 (K213649). Both CT systems are identical in terms of the high resolution, multi row, 85 cm bore, and 60 cm field of view. 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 interventional radiology package should not be used in an operating room during surgery.

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.

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 64 (K213649).

We modified the cleared BodyTom 64 (K213649) within our design controls to include technology improvements, specifically the introduction of interventional radiology package.

The indications for use between the subject device and the predicate device (K213649) only vary slightly, in that the subject device includes an interventional radiology package. The subject device still contains the same technology and basic functionality as the predicate device (K213649), and therefore, safety and efficacy are not of a concern. Please find both the subject and predicate device indications for use below.

BodyTom 64 (Subject Device)	**BodyTom 64 (Predicate – K213649)**
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.	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.

The inclusion of the interventional radiology package is a software update, and the CT system remains the same from a hardware standpoint.

<u>Similarities</u>

- Design: The BodyTom 64 is identical in design characteristics to its previous version and shares all of the control system designs and features of the cleared predicate device.
- Components: The BodyTom 64 uses the same components as the predicate device such as x-ray generator, collimator, slip ring and power system.

<u>Differences</u>

The following differences exist between the subject device (BodyTom 64) and its previously cleared version, predicate device (K213649).

- The software revision has undergone few updates since the BodyTom 64 (K213649) 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. The BodyTom 64 software functions are similar to the predicate BodyTom 64 (K213649) device. The image quality algorithms were updated, specifically for helical imaging.

- Interventional radiology package is included along with Instant Repeat feature. The base interventional radiology package is identical to the reference device, BodyTom Elite (K170238) while the Instant Repeat feature is new.

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.

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
19-46	AAMI / ANSI ES 60601-1	Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance	2012
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	2014

FDA Recognition Number	Standard	Description	Version
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	2013
5-132	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
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

FDA Recognition Number	Standard	Description	Version
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
2-174	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

FDA Recognition Number	Standard	Description	Version
12-352	NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM) Set	2023
21 CFR subchapter J § 1020.30	FDA	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic x-ray systems and their major components	2024
21 CFR subchapter J § 1020.33	FDA	Performance Standards for Ionizing Radiation Emitting Products: Computed tomography (CT) equipment	2024

The BodyTom 64 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, 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

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 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 substantial equivalence of BodyTom 64.

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.

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.

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.

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 has comparable image quality with its previous version, predicate device (K213649) and meets all the image quality criteria that are used for testing.

Conclusion

Both the proposed device (BodyTom 64) and the predicate device BodyTom 64 (K213649) are CT systems that are used for pediatric and adult imaging (similar 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.