



September 22, 2026

Samsung HME America, Inc., dba NeuroLogica Corp.
% Ninad Gujar
Vice President
14 Electronics Ave.
DANVERS, MA 01923

Re: K261125

Trade/Device Name: BodyTom 64 (NL4100); OmniTom Elite (NL5000)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: April 5, 2026
Received: April 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

A large, light blue 'FDA' watermark is visible in the background. Overlaid on it is a handwritten signature in black ink that reads '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

Indications for Use

510(k) Number (if known)

K261125

Device Name

BodyTom 64 (NL4100); OmniTom Elite (NL5000)

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.

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 the 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.

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K261125

510(k) Summary

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

Date Prepared: March 31, 2026

Submitter

Samsung HME America, Inc., dba NeuroLogica Corp.
14 Electronics Avenue, Danvers, MA 01923

Establishment Registration

3004938766

Manufacturing Site

Samsung HME America, Inc., dba NeuroLogica Corp.
14 Electronics Avenue, Danvers, MA 01923

Official Correspondent & Contact Person

Dr. Ninad Gujar
Vice President, Regulatory, Quality and Compliance
Telephone: 978-564-8632
E-mail: ngujar@samsunghme.com

Device

Trade Name (Device Model):	BodyTom 64 (NL4100); OmniTom Elite (NL5000)
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 (K242811)
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Reference Device

Trade Name: OmniTom Elite (K233767)
Classification Name: Computed Tomography X-ray System
Product Code: JAK
Device Classification: Class II (per 21 CFR § 892.1750)

Device Description

This submission is for the Samsung Weighted Filtered Back Projection (S-FBP) algorithm. This applies to both BodyTom 64 and OmniTom Elite computed tomography (CT) systems. BodyTom 64 has 85 cm bore, and 60 cm field of view while the OmniTom Elite is a 16 row, 40 cm bore, and 30 cm field of view. S-FBP algorithm is identical for OmniTom Elite and BodyTom 64 and applies to both products.

Both CT systems are similar in terms of the high resolution scanning with a 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 updated S-FBP reconstruction algorithm implements a weighted filtered back projection method, which is an established extension of the Feldkamp-Davis-Kress (FDK) reconstruction algorithm. Both methods belong to the same class of approximate cone-beam reconstruction techniques and share the same fundamental reconstruction framework. The S-FBP algorithm applies additional projection-domain weighting functions to improve reconstruction performance for helical acquisition geometry. The underlying reconstruction framework (filtered back projection with 1D filtering and back projection) remains unchanged.

The CT devices with S-FBP are effective at reducing artifacts, particularly the Z-axis artifact that appears as a spiral pattern in helical scans and the cone-beam artifacts that plague FDK. By using this weighting, S-FBP significantly improved image quality and reduces noise, especially for large cone angles. The weighting in S-FBP made it more robust to variations in pitch. By correcting data inconsistencies, S-FBP demonstrated a statistically significant reduction in image noise. This improved signal-to-noise ratio resulted in better image contrast.

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.

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 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

The BodyTom 64 and OmniTom Elite, for its intended use, is of comparable type in design, material, functionality, and technology and is substantially equivalent to the cleared predicate device respectively – BodyTom 64 (K242811) and OmniTom Elite (K233767).

We modified only the software for the cleared BodyTom 64 (K242811) and OmniTom Elite (K233767) within our design controls to include technology improvements, specifically the S-FBP reconstruction algorithm. There are no hardware changes. There is no change in the indications of use for either or the devices and the algorithm change applies to both.

The indications for use between the subject device and the respective predicate devices is identical. The subject device still contains the same technology and basic functionality as the predicate device, and therefore, safety and efficacy are not of a concern.

BodyTom 64 (Subject Device with S-FBP algorithm)	BodyTom 64 (Predicate – K242811 with FDK algorithm)
The BodyTom 64 system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged	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.	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.
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OmniTom Elite (Subject Device with S-FBP algorithm)	OmniTom Elite (Predicate – K233767 with FDK algorithm)
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 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.	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 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.

Similarities

- Design: The BodyTom 64 and OmniTom Elite are 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 and OmniTom Elite uses the same components as the predicate device such as x-ray generator, collimator, slip ring and power system.

Differences

- Only the updated imaging reconstruction algorithm is different between the subject device (BodyTom 64 with S-FBP) and its previously cleared version, predicate device (K242811) and (OmniTom Elite with S-FBP) and its previously cleared version, predicate device (K233767).

S-FBP remains within the class of filtered backprojection-based reconstruction method however differs from standard FDK in that it incorporates an additional weighting function applied to projection data before reconstruction. This weighting function provides:

(1) correction for helical scan trajectory geometry, and (2) management of data redundancy inherent in helical acquisition. These modifications result in improved image quality, including reduced cone-beam artifacts, suppression of Z-axis spiral artifacts and improved signal-to-noise ratio – particularly for wide cone-angle and varied-pitch helical acquisitions.

These differences do not raise new questions of safety and effectiveness. The S-FBP algorithm shares the same intended use and fundamental technological characteristics as cleared predicate FDK-class reconstruction algorithms. The performance improvements achieved are quantitative in nature and consistent with incremental developments within the FDK algorithm family.

The internal verification and validation activities and external testing of product safety and EMC / EMI was completed successfully. This change in algorithm does not alter dose output, acquisition parameters or system hardware. The S-FBP update does not have 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 and OmniTom Elite CT systems 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 and OmniTom Elite CT systems are designed and manufactured to comply with the FDA Code of Federal Regulations Title 21 Part 820: Quality Management System Regulation (QMSR), incorporating ISO 13485:2016 by reference. 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

FDA Recognition Number	Standard	Description	Version
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
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

FDA Recognition Number	Standard	Description	Version
5-134	ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - 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
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

FDA Recognition Number	Standard	Description	Version
NR	NEMA XR 29	Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management	2013
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 S-FBP algorithm was designed in accordance with the following FDA Guidance documents:

- *Content of Premarket Submissions for Device Software Functions (June 2023)*
- *Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions (Sept 2023)*
- *Electronic Submission Template (eSTAR) (Oct 2023)*
- *Off-The-Shelf Software Use in Medical Devices (Aug 2023)*
- *Guidance for Medical X-ray Imaging Devices Conformance with IEC Standards (May 2019)*
- *Pediatric X-ray Premarket Notifications (Nov 2017)*
- *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions (Feb 2026)*
- *Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors (Aug 2023)*
- *Medical Device Accessories – Describing Accessories and Classification Pathways (Dec 2017)*
- *Computer Software Assurance for Production and Quality System Software (Sept 2022)*

- *Guidance for Postmarket Management of Cybersecurity in Medical Devices, December 2016*
- *Guidance for Deciding When to Submit a 510(k) for a Change to an Existing Device, (Oct 2017)*
- *Deciding When to Submit a 510(k) for a Software Change to an Existing Device (Oct 2017)*
- *Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) (July 2021)*
- *Applying Human Factors and Usability Engineering to Medical Devices (Feb 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 and OmniTom Elite CT systems 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 and OmniTom Elite CT systems. The verification/validation testing ensured substantial equivalence of BodyTom 64 and OmniTom Elite CT systems.

Design verification and design validation testing was performed to confirm all design and user requirements were met. The proposed S-FBP algorithm for BodyTom 64 and OmniTom Elite CT systems was shown to meet all requirements.

The BodyTom 64 and OmniTom Elite CT systems 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 software algorithm change in the proposed device has comparable image quality with its previous version, predicate device and meets all the image quality criteria that are used for testing.

Phantom based evaluation

Phantom based study was conducted using an American College of Radiology phantom, where the subject S-FBP helical reconstruction algorithm performed better than the predicate FDK helical reconstruction for all image related purposes especially in uniformity, noise, and low contrast resolution.

Based on this internal testing, under controlled phantom condition representative of clinical operating ranges, for BodyTom 64 with S-FBP, the Noise was improved by approximately 29% and the Contrast-to-Noise Ratio (CNR) was improved by approximately 35% when transitioning from the FDK to the S-FBP reconstruction method for BodyTom 64

For OmniTom Elite – similar to BodyTom 64, the inclusion of S-FBP is a software update, and the CT system remains the same from a hardware standpoint. All testing was repeated for OmniTom Elite with similar results. For image quality metrics, OmniTom Elite with S-FBP, the Noise was improved by approximately 32% and the CNR was improved by approximately 55% when transitioning from the FDK to the S-FBP reconstruction method.

Clinical evaluation

Clinical study was conducted for evaluation of the subject device with S-FBP algorithm. All study protocols were performed in accordance with the relevant regulations and the guidelines. The images were reviewed by independent board-certified practicing radiologists and confirmed diagnostic quality of the images demonstrating the effectiveness of the subject device for clinical scanning. The S-FBP algorithm was able:

- reduce image noise and improve texture smoothness
- eliminate helical artifacts, including rotating shading patterns and Z-axis horizontal streaking in MPR views
- mitigate complex geometric artifacts, such as the "windmill" artifacts in cranial imaging and motion-induced dislocations in the thorax

The clinical scans indicate the ability of the S-FBP algorithm to generate diagnostically acceptable images, which are equivalent to those produced by predicate device. The subject device clinical

benefits outweigh the risks and as such the device should be considered safe for its intended use and performs like other CT devices currently on the market. The clinical evaluation demonstrates performance of the CT device using the S-FBP algorithm, when used under the conditions and for the purposes intended.

Conclusion

Both the proposed device - BodyTom 64 and OmniTom Elite CT systems and the respective previously cleared version, predicate devices - BodyTom 64 (K242811) and OmniTom Elite (K233767) 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 S-FBP reconstruction algorithm represents a well-characterized, incremental improvement to a cleared algorithm technology, differing only in weighting methodology while retaining the same reconstruction principles, computational approach and intended clinical use.

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 CT system performs as well in its intended use as similar devices currently on the market.