December 17, 2025

Neosoma, Inc.
% Meritxell Martinez
Regulatory Specialist
Innolitics, LLC
1101 West 34th St.
#550
Austin, Texas 78705

Re: K252922
Trade/Device Name: Neosoma Brain Mets
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB, QIH
Dated: November 20, 2025
Received: November 21, 2025

Dear Meritxell Martinez:

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252922

Device Name
Neosoma Brain Mets

Indications for Use *(Describe)*
The Neosoma software uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) known or previously diagnosed brain tumors on MRI images for qualified and trained medical professionals.

The technology is meant for informational purposes only and not intended to replace the clinician's current standard practice of manual contouring. The software does not alter the original MRI image, nor is it intended to be used to detect tumors for diagnosis. The software is intended to be used on adult patients only.

When using the Neosoma software in a radiation oncology planning workflow, or other clinical workflows, it is intended for generating Gross Tumor Volume (GTV) contours. For all clinical workflows, medical professionals must finalize (confirm or modify) the contours generated by the Neosoma software, as necessary, using an external platform available at the facility that supports DICOM viewing/editing functions, such as image visualization software and treatment planning system.

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.

neosoma	**510(k) Summary- K252922**

1 GENERAL INFORMATION

Company Name	Neosoma, Inc.
Address	44 Farmers Row, Groton, MA 01450
Phone Number	877-636-7662
Company Representative	Kenneth Kolodziej, CEO, Neosoma
Email	ken.kolodziej@neosomainc.com
Primary Correspondent	Meritxell Martinez, Innolitics
Primary Correspondent Email	fda@innolitics.com
Date Summary Prepared	September 12th, 2025

2 DEVICE INFORMATION

Trade Name	Neosoma Brain Mets
Common Name	Automated radiological image processing software
Product Code	QKB, QIH
Regulation Number	21 CFR 892.2050
Class	Class II
Panel	Radiology

3 PREDICATE DEVICE

Device Name	VBrain
Manufacturer	Vysioneer Inc.
510(k) Number	K203235
Product Code	QKB

Regulation Number	892.2050
Regulation Name	Medical image management and processing system.
Regulatory Class	Class II
Review Panel	Radiology

4 REFERENCE DEVICE

Device Name	NS-HGlio
Manufacturer	Neosoma Inc.
510(k) Number	K221738
Product Code	QIH
Regulation Number	892.2050
Regulation Name	Medical image management and processing system.
Regulatory Class	Class II
Review Panel	Radiology

5 DEVICE DESCRIPTION

Neosoma Brain Mets is a Software as a Medical Device (SaMD) that is designed specifically for the semi-automatic segmentation of previously diagnosed brain metastases. This functionality is applicable to the T1 post-contrast sequence, which is routinely obtained in clinical practice through brain Magnetic Resonance Imaging (MRI).

It is important to note that the standard criterion for diagnosing brain metastasis includes the presence of a known primary cancer that has been identified as having metastasized to the brain. Accordingly, Neosoma Brain Mets is not intended for use with images representing other types of brain lesions.

Furthermore, Neosoma Brain Mets is specifically designed for use in adult patient populations (age 22 and older). As such, its usage should be confined to this demographic to ensure compliance with its intended use parameters and to maximize the accuracy and relevance of its results.

The analysis performed by the AI includes semi-automatic segmentation of the metastasis based on pixel signal intensity. The volumes are calculated using non-machine-learning post-processing from the AI segmentation output. For this segmentation, the software requires one MRI sequence (T1 post-contrast) as input, and it outputs post-processed images that contain color-coded segmentations, as well as volumetric measurements.

6 INDICATIONS FOR USE

The Neosoma software uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) known or previously diagnosed brain tumors on MRI images for qualified and trained medical professionals.

The technology is meant for informational purposes only and not intended to replace the clinician's current standard practice of manual contouring. The software does not alter the original MRI image, nor is it intended to be used to detect tumors for diagnosis. The software is intended to be used on adult patients only.

When using the Neosoma software in a radiation oncology planning workflow, or other clinical workflows, it is intended for generating Gross Tumor Volume (GTV) contours. For all clinical workflows, medical professionals must finalize (confirm or modify) the contours generated by the Neosoma software, as necessary, using an external platform available at the facility that supports DICOM viewing/editing functions, such as image visualization software and treatment planning system.

7 SUBSTANTIAL EQUIVALENCE DISCUSSION

Characteristic	Subject Device Neosoma Brain Mets	Predicate Device VBrain (K203235)	Reference Device NS-HGlio (K221738)	Substantial Equivalence Discussion
Regulation and Product Code	21 CFR 892.2050 QIH & QKB	21 CFR 892.2050 QKB	21 CFR 892.2050 QIH	All devices fall under the same regulation 21 CFR 892.2050. The subject device also falls under the same product codes as the predicate and reference devices.
Indications for Use	The Neosoma software uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) known or previously diagnosed brain tumors on MRI images for qualified and trained medical professionals. The technology is meant for informational purposes only and not intended to replace the clinician's current standard practice of manual contouring. The software does not	VBrain is a software device intended to assist trained medical professionals, during their clinical workflows of radiation therapy treatment planning, by providing initial object contours of known (diagnosed) brain tumors (i.e., region of interest, ROI) on axial Tl contrast enhanced brain MRI images. VBrain uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) brain tumors on MRI images	NS-HGlio is intended for the semi-automatic labeling, visualization, and volumetric quantification of high-grade brain glioma (WHO grade 3 astrocytoma, WHO grade 4 astrocytoma and WHO grade 4 glioblastoma) from a set of standard MRI images of male or female patients 18 years of age or older who are known to have pathologically proven high-grade glioma. Volumetric measurements may be	The indications for use of Neosoma software and VBrain are highly similar in scope, intended user, and clinical application. Both devices are software tools designed to assist trained medical professionals, particularly in the context of radiation therapy treatment planning and related clinical workflows, by providing semi-automatic contouring of known or previously diagnosed brain tumors on MRI images. Both employ artificial intelligence (deep learning neural networks) to generate Gross Tumor Volume (GTV) contours, are intended for informational purposes only, do not replace standard manual contouring practices, do not alter the original MRI image, and are not intended for tumor detection or diagnosis.

	alter the original MRI image, nor is it intended to be used to detect tumors for diagnosis. The software is intended to be used on adult patients only. When using the Neosoma software in a radiation oncology planning workflow, or other clinical workflows, it is intended for generating Gross Tumor Volume (GTV) contours. For all clinical workflows, medical professionals must finalize (confirm or modify) the contours generated by the Neosoma software, as necessary, using an external platform available at the facility that supports DICOM viewing/editing functions, such as image visualization software and	for trained medical professionals' attention, which is meant for informational purposes only and not intended for replacing their current standard practice of manual contouring process. VBrain does not alter the original MRI image, nor does it intend to be used to detect tumors for diagnosis. VBrain is intended only for generating Gross Tumor Volume (GTV) contours of brain metastases, meningiomas, and acoustic neuromas on axial Tl contrast-enhanced MRI images; It is not intended to be used with images of other brain tumors. The user must know the tumor type when they use VBrain.	compared to past measurements if available. NS-HGlio is not to be used for primary diagnosis, and is intended to be used by qualified clinical personnel as an additional source of information and is not intended to be the sole diagnostic metric.	

	treatment planning system.			
Modality	MRI: T1 postcontrast	MRI: T1 postcontrast	MRI: T1 precontrast, T1 postcontrast, T2 and T2-FLAIR	Same as the predicate device.
Anatomical Target	Brain	Brain	Brain	Same.
Image Review	2D and 3D	2D and 3D	2D and 3D	Same.
Segmentation	ML based semi-automatic segmentation of brain metastasis	ML based semi-automatic and manual segmentation of brain metastasis	ML based semi-automatic segmentation of brain high grade glioma	Same as the predicate device.
Quantification	Volumetric measurement of the brain metastasis	Volumetric measurement of the brain metastasis	Volumetric measurement of the brain high grade glioma	Same as the predicate device.
Output	Provides volumetric measurements of brain metastasis. Includes segmented color overlays of brain metastasis and reports.	Provides volumetric measurements of brain metastasis. Includes segmented color overlays of brain metastasis and reports.	Provides volumetric measurements of brain high grade glioma. Includes segmented color overlays.	Same as predicate device.
Architecture	Leverages a common	Unknown.	Same pre and post	The subject device uses the same pre and post

	pre and post processing pipeline from K221738 (the reference device).		processing pipeline as subject device.	processing pipeline components (e.g. MRI normalization, atlas registration, and skull stripping) as the reference device.

8 PERFORMANCE DATA

a. Software Verification and Validation

Performance of Neosoma Brain Mets have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/AC:2015 - Medical device software – Software life cycle processes, in addition to the 2023 FDA Guidance document, “Content of Premarket Submissions for Device Software Functions”.

b. Clinical Performance

Neosoma Brain Mets was evaluated in a retrospective, blinded, multicenter study. The testing dataset consisted of 70 subjects and 70 MRIs (one MRI per subject) used for the evaluation of the machine learning model performance. The test dataset was acquired from medical sites (inside and outside of the US) that were not included in the training dataset to ensure device generalizability. The data were acquired using standard of care MRI protocols on Canon, GE, Siemens, and Toshiba scanners at both 1.5T and 3.0T. Imaging parameters for the axial T1 post-contrast sequence were representative of routine clinical practice (slice thickness ranging from 0.5–5 mm, pixel spacing ranging from 0.45–1.12 mm, and spacing between slices ranging from 0.5–5.5 mm).

Following the real-world prevalence of brain metastases, the data consisted of subjects within the age range of 28 to 84 and covering a diverse group of ethnic backgrounds. The distribution of primary cancers in the testing dataset was consistent with the known epidemiology of brain metastases.

The reference standard (ground truth) was established using three US board certified neuroradiologists with expertise in measuring brain metastases. The dataset was evaluated using the following quantitative endpoints:

- Sensitivity rate, to assess the true positive rate of lesion identification
- False Positive Rate, to assess the number of false positive lesions per MRI
- DSC (Dice Similarity Coefficient), to assess the degree of overlap between device output and the reference standard.
- 95th percentile Hausdorff Distance (HD95) for true-positive lesions, to assess the maximum boundary distance between the device segmentation and the reference standard.
- Mean Surface Distance (MSD) for true-positive lesions, to assess the average distance between device and reference standard surfaces.

Metric	Acceptance Criteria	Performance Results
Sensitivity	≥ 0.85	0.90 with 95% CI of 0.87 - 0.94

False Positive Rate	≤ 5 false positive lesions per MRI	0.57 lesions per MRI with 95% CI of 0.35 - 0.80
DSC	≥ 0.70	0.86 with 95% CI of 0.83 - 0.89
HD95	≤ 2.94 mm	1.78 mm with 95% CI of 1.02 - 2.54
MSD	≤ 0.66 mm	0.36 mm with 95% CI of 0.16 - 0.56

A subgroup analysis of the data based on site, imaging manufacturer, field strength, patient race and ethnicity, age, gender, primary cancer, and site geography was conducted. Overall, the data demonstrated that the device performance is consistent across all sub-groups.

9 CONCLUSION

Based on the indications for use, technological characteristics, and the conclusions drawn from performance testing, the results demonstrate that Neosoma Brain Mets performs as intended and supports a finding of substantial equivalence.