September 27, 2022

Neosoma, Inc.
% Aly Abayazeed
Co-founder and Chief Medical Officer
44 Farmers Row
GROTON MA 01450

Re: K221738
Trade/Device Name: NS-HGlio
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: September 1, 2022
Received: September 2, 2022

Dear Aly Abayazeed:

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,

**Daniel M. Krainak, Ph.D.**
Assistant Director
Magnetic Resonance and Nuclear Medicine 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)*
K221738

Device Name
NS-HGlio

Indications for Use *(Describe)*
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 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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

## 1.1 General Information

K221738

| | |
|---|---|
| **510(k) Sponsor** | Neosoma, Inc. |
| **Address** | 44 Farmers Row<br>Groton, MA 01450 |
| **Correspondence Person** | Aly H. Abayazeed, MD.<br>Co-founder and Chief Medical Officer |
| **Contact Information** | aly.abayazeed@neosomainc.com<br>443-804-8096 |
| **Date Prepared** | June 14, 2022 |

## 1.2 Proposed Device

| | |
|---|---|
| **Proprietary Name** | NS-HGlio |
| **Classification Name** | Automated Radiological Image Processing Software |
| **Regulation Number** | 21 CFR 892.2050 |
| **Product Code** | QIH |
| **Regulatory Class** | II |

## 1.3 Predicate Device

| | |
|---|---|
| **Proprietary Name** | NeuroQuant |
| **Premarket Notification** | K170981 |
| **Classification Name** | Automated Radiological Image Processing Software |
| **Regulation Number** | 21 CFR 892.2050 |
| **Product Code** | LLZ |
| **Regulatory Class** | II |

## 1.4 Device Description

NS-HGlio is a non-invasive software as a medical device (SaMD) tool intended for labeling, visualization, and volumetric quantification of high-grade brain gliomas for a population that has been pathologically diagnosed to have brain tumors. The device is used

as a tool by clinicians in determining the patient's disease conditions on pre- and post-operative MRI images. The device is not used for primary diagnosis.

NS-HGlio device takes as an input imported Digital Imaging and Communications in Medicine (DICOM) images of high-grade brain glioma acquired with standard brain tumor MRI protocols and uses a deep learning methodology to semi-automatically label the different subcomponents of the high-grade glioma. Results are displayed on a Neosoma viewing software. Optionally, the software connects to clinicians' applications (e.g., PACS).

### 1.5 Indications for Use

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 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.

### 1.6 Comparison of Technological Characteristics with the Predicate Device

| **Feature/ Function** | **Subject Device:** NS-HGlio | **Predicate Device** NeuroQuant manufactured by CorTechs Labs K170981 |
|---|---|---|
| Type of Scans | MRI:<br>Acquired using four different MRI sequences either in 2D or 3D using a specified protocol<br>(T1 pre-contrast, T1 post-contrast, T2 and FLAIR) | MRI:<br>Neuroquant: 3D T1 pre-contrast scans acquired with specified protocols<br>Lesionquant: 3D FLAIR scan acquired with specified protocol |
| Intended Anatomy | Brain | Brain |
| Lesion Review | 2D and 3D | 2D |

| **Feature/ Function** | **Subject Device:** NS-HGlio | **Predicate Device** NeuroQuant manufactured by CorTechs Labs K170981 |
|---|---|---|
| Segmentation | Semi-automatic and manual segmentation of high-grade glioma | Semi-automatic and manual segmentation of brain structures |
| Quantification | Volumetric measurement of the sub-components of high-grade glioma | Automated measurement of brain tissue volumes and structures and lesions |
| Output | - Provides volumetric measurements of high-grade brain glioma and sub-components<br>- Includes segmented color overlays of sub-components and reports<br>- Automatically compares results to prior scans when available | - Provides volumetric measurements of brain structures and lesions<br>- Includes segmented color overlays and morphometric reports<br>- Automatically compares results to reference percentile data and to prior scans when available |
| Image Format | DICOM | DICOM |
| Report | YES | YES |

### 1.7 Performance Data

Safety and performance of NS-HGlio 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 FDA Guidance document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

The testing dataset consisted of 33 subjects and 132 MRIs used for the evaluation of the machine learning model performance. The test dataset was acquired from medical sites that were not included in the training dataset to ensure device generalizability. The data were acquired using standard of care MRI protocols on Siemens, GE, and Toshiba scanners. Following the real world prevalence of the high grade glioma, the data consisted of more males than females within the age range of 18 to 79 and covering a diverse group of ethnic backgrounds.

The reference standard (ground truth) was established using three US board certified neuroradiologists with expertise in measuring high grade gliomas. The dataset was evaluated using the DSC (Dice Similarity Coefficient) assessing the degree of overlap between device output and the reference standard as well as the Intraclass correlation coefficient (ICC) of the device output volumes and the reference standard.

The device achieved a mean DSC of 0.88 with 95% CI of 0.86-0.90 on preoperative imaging and 0.80 with 95% CI of 0.77-0.83 on postoperative imaging which is higher than the mean DSC of the average of the three experts for the same task, which was 0.84 on preoperative imaging and 0.74 for postoperative imaging respectively. The mean ICC was 0.98 with 95% CI of 0.97-0.99.

## 1.8 Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, NS-HGlio raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.