July 23, 2025

Olea Medical S.A.S.
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K243681
Trade/Device Name: Neuro Insight V1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 7, 2025
Received: July 7, 2025

Dear John J. Smith:

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,

Ningzhi Li -S Digitally signed by Ningzhi Li -S

for
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: 07/31/2026
See PRA Statement below

Submission Number *(if known)*

K243681

Device Name

Neuro Insight V1.0

Indications for Use *(Describe)*

Neuro Insight V1.0 is an image processing solution. It is intended to assist appropriately trained medical professionals in their analysis workflow on neurological MRI images.

Neuro Insight V1.0 is composed of two subsets, including an image processing application package (NeuroPro) and an optional user interface (Neuro Synchronizer).

NeuroPro is an image processing application package that computes maps, extracts and communicates metrics which are to be used in the analysis of multiphase or monophase neurological MR images.

NeuroPro can be integrated and deployed through technical integration environment, responsible for transferring, storing, converting formats and displaying of DICOM imaging data.

Neuro Synchronizer is an optional dedicated interface allowing the viewing, manipulation, and comparison of neurological medical imaging and/or multiple time-points, including post-processing results provided by NeuroPro or any other results from compatible processing applications.

Neuro Synchronizer is a medical image management application intended to enable the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided through the technical integration environment as inputs to the application to reprocess outputs. If necessary, Neuro Synchronizer provides the user with the option to validate the information.

Neuro Synchronizer can be integrated in compatible technical integration environments.

The device does not alter the original medical image. Neuro Insight V1.0 is not intended to be used as a standalone diagnostic device and should not be used as the sole basis for patient management decisions. The results of Neuro Insight V1.0 are intended to be used in conjunction with other patient information and based on professional judgment to assist with reading and interpretation of medical images. Users are responsible for viewing full images per the standard of care.

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.

510(K) SUMMARY

Olea Medical's Neuro Insight V1.0

(K243681)

Submitter

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Date Prepared: July 22, 2025

Device Identification

Name of Device:	Neuro Insight V1.0
Common Name:	Medical image management and processing system
Classification Name:	System, Image Processing, Radiological
Regulation No:	892.2050
Product Code:	LLZ

Legally Marketed Predicate Device

510(k):	K152602
Trade Name:	Olea Sphere V3.0
Manufacturer:	Olea Medical
Product Code:	LLZ

Legally Marketed Reference Devices

510(k):	K223502
Trade Name:	MR Diffusion Perfusion Mismatch V1.0
Manufacturer:	Olea Medical
Product Code:	LLZ

510(k):	K223532
Trade Name:	Olea S.I.A Neurovascular V1.0
Manufacturer:	Olea Medical
Product Code:	LLZ

Device Description Summary

Neuro Insight (NEU_INS_MM) V1.0 product is a neurological image analysis solution, composed of several image processing applications and optional visualization and manipulation features.

Neuro Insight V1.0 is composed of two subsets:
• NeuroPro (NEU_PRO_MR) as an image application package, responsible for the processing of specific neurological MR Images.
• Neuro Synchronizer (NEU_HMI_MM) as an optional image analysis environment, that provides the user interface which has visualization and manipulation tools and allows the user to edit the parameters of compatible applications.

Neuro Insight does not alter the original medical image and is not intended to be used as a diagnostic device.

Intended Use / Indications for Use

Neuro Insight V1.0 is an image processing solution. It is intended to assist appropriately trained medical professionals in their analysis workflow on neurological MRI images.

Neuro Insight V1.0 is composed of two subsets, including an image processing application package (NeuroPro) and an optional user interface (Neuro Synchronizer).

NeuroPro is an image processing application package that computes maps, extracts and communicates metrics which are to be used in the analysis of multiphase or monophase neurological MR images.

NeuroPro can be integrated and deployed through technical integration environment, responsible for transferring, storing, converting formats and displaying of DICOM imaging data.

Neuro Synchronizer is an optional dedicated interface allowing the viewing, manipulation, and comparison of neurological medical imaging and/or multiple time-points, including post-processing results provided by NeuroPro or any other results from compatible processing applications.

Neuro Synchronizer is a medical image management application intended to enable the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided through the technical integration environment as inputs to the application to reprocess outputs. If necessary, Neuro Synchronizer provides the user with the option to validate the information.

Neuro Synchronizer can be integrated in compatible technical integration environments.

The device does not alter the original medical image. Neuro Insight V1.0 is not intended to be used as a standalone diagnostic device and should not be used as the sole basis for patient management decisions. The results of Neuro Insight V1.0 are intended to be used in conjunction with other patient information and based on professional judgment to assist with reading and interpretation of medical images. Users are responsible for viewing full images per the standard of care.

Indications for Use Comparison

Both Neuro Insight V1.0 and Olea Sphere® V3.0 are user-defined software analysis tools used for the analysis of magnetic resonance imaging (MRI) studies. Both devices are intended for use in Clinical/Hospital Environment, by any trained professional. Importantly, neither software product is used for diagnosis. Patient management decisions should not be based solely on the results of either software.

The minor difference in the indications for use between the two devices is that Neuro Insight V1.0 subject device provides processing capabilities for MR only whereas Olea Sphere® V3.0 predicate device provides processing capabilities for both MR and CT.

Neuro Insight V1.0 subject device represents a subset of Olea Sphere® V3.0 predicate device. Therefore, the indication for use of Neuro Insight V1.0 is considered substantially equivalent to Diffusion, Perfusion, Olea Vision, Analysis and Longitudinal Analysis Mono modules of Olea Sphere® V3.0.

Technological Comparison

Both Neuro Insight V1.0 and Olea Sphere V3.0 have similar technological characteristics as they both:
• provide processing capabilities for the analysis of FLAIR, T1, T2, T1g, diffusion and DSC perfusion series;
• are designed to be able to process FLAIR, T1, T2, T1g, diffusion and DSC perfusion series;
• are able to provide the same outputs for FLAIR, T1, T2, T1g, diffusion and DSC perfusion metrics (CBV, CBF, MTT, TTP, Tmax/Delay, CBV_corr, K2, tMIP);
• provide the same standard viewing tools and edition of parameters that are optional inputs of compatible docker applications. Currently, with NeuroPro being the only compatible application, the only editable parameter is arterial input function (AIF) selection. As with the FDA-cleared Olea S.I.A Neurovascular V1.0 (K223532), the user can adjust the AIF automatically calculated by the application (by NeuroPro) as needed and request a recalculation of the results using the desired value. The implementation and management of this feature are exactly the same as in Olea S.I.A Neurovascular V1.0.

The minor differences in the technological characteristics between the two devices are:

- Neuro Insight V1.0 uses a motion correction algorithm based on a 3D rigid method before DSC perfusion maps computation, while Olea Sphere® V3.0 uses a 2D rigid motion correction algorithm. This difference does not impact the calculation method of the outputs. This motion correction algorithm based on a 3D rigid method has already been cleared as a component of MR Diffusion Perfusion Mismatch V1.0 (Olea Medical, France), FDA-cleared (K223502).

- Neuro Insight V1.0 uses a brain extraction tool (BET) based on a 3D deep learning algorithm before DSC perfusion maps computation, while Olea Sphere® V3.0 uses thresholds based on a histogram analysis of the MR images. For more information about this deep learning testing and validation process please refer to *"About Deep learning algorithm for BET"* below. This difference does not impact the calculation method of the outputs.

- Neuro Insight V1.0 uses co-registration algorithms based on 3D rigid 6-dof transformation, while Olea Sphere® V3.0 uses IPP IOP DICOM tags to locate and align volumes.

However, these minor differences in the technological characteristics between both devices do not raise different questions of safety and effectiveness.

About Deep learning algorithm for BET

To filter out the brain and the cerebrospinal fluid (CSF), surrounding noise and background pixels on raw images, MR DSC Perfusion includes a brain extraction algorithm for MR PWI series. This brain extraction algorithm uses a 3D U-Net architecture, consisting of 6 layers (16, 32, 64, 128, 256, 512), and was optimized using both DICE and Tversky metrics. It was trained with 362 manually annotated MR volumes split in train (199 cases), validation (63 cases) and test (100 cases) dataset. The database was sourced to ensure broad representativeness depending on the manufacturer, magnetic field, acquisition parameters, origin, patient age and sex. The manual segmentation was performed by expert clinicians following criteria defined by a US board certified neuroradiologist. Two labels were used: one for the brain tissue and one for the voxels who do not belong to brain tissue (background).

Cases were collected from multiple MRI system manufacturers: 114 cases from GE Healthcare (48% at 1.5T, 52% at 3T), 127 from Siemens (64% at 1.5T, 36% at 3T), 95 from Philips (70% at 1.5T, 30% at 3T), 25 from Canon formerly Toshiba (60% at 1.5T, 40% at 3T), and one case with unknown manufacturer information due to severe DICOM anonymization.

Patient demographics comprised 51% male subjects, 43% female subjects, with 6% lacking gender information due to DICOM anonymization protocols. Age information was limited due to anonymization processes, with over half of the dataset missing age data. Among available cases, the mean age was 60 years with a range spanning from 14 to 100 years, representing a diverse patient population across different age groups.

Ground truth brain masks were created by experienced clinicians following a standardized annotation protocol defined by a U.S. board-certified neuroradiologist. The protocol included all brain structures—hemispheres and lesions—while explicitly excluding non-brain anatomical elements such as the skull, eyeballs, and optic nerves. Each segmentation was reviewed by a neuroradiologist and a research engineer to ensure consistency and accuracy across the dataset.

A 5-fold cross-validation procedure was applied to assess performance stability and generalizability across different scanner types and patient profiles.

The achieved average DICE coefficient of 0.97, ranging from 0.907 to 0.988, exceeds the predetermined acceptance threshold of 0.95. These results demonstrate excellent spatial overlap between automated segmentations and expert-annotated ground truth masks, as well as high segmentation accuracy and consistent reliability across diverse clinical scenarios.

These conclusions confirm the algorithm's robustness and reliability, enabling accurate and reproducible brain extraction as part of automated neuroimaging workflows.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Olea Medical has conducted validation testing of the Neuro Insight V1.0. Internal verification, usability and validation testing confirms that the product specifications are met, and support of the substantial equivalence of the intended use and technological characteristics to the predicate device.

Neuro Insight V1.0 has been validated to ensure that the system, as a whole, provides all the capabilities necessary to operate according to its intended use and in a manner substantially equivalent to the predicate device.

The following performance evaluations were conducted:

- Product risk assessment;
- Software modules verification tests;
- Usability assessment;
- Software validation test.

All software features of Neuro Insight V1.0 have undergone verification and usability testing to ensure proper performance and safe integration into clinical workflows. Specific attention was given to features identified through risk analysis, which were evaluated with consideration of human factors. Testing was performed in alignment with the intended use and user instructions. No issues were reported by operators during testing, and no clinically significant failures or incidents occurred.

Based on the performance testing, the Neuro Insight V1.0 has a safety and effectiveness profile that is similar to the predicate device.

Neuro Insight V1.0 was quantitatively and qualitatively compared to Olea Sphere® V3.0 software (Olea Medical®, FDA-cleared - K152602), identified as the predicate device.

Two main features were evaluated:

- Parametric maps computation: ADC, CBF, CBV, CBV_Corr, K2, MTT, TTP, Tmax/Delay, tMIP;

  Neuro Insight V1.0 and Olea Sphere® V3.0 were quantitatively and qualitatively compared by three US board-certified neuroradiologists using 30 anonymized brain MRI cases. For each DWI and DSC parametric maps, the statistical and/or visual analysis of the results derived from this comparison supported the substantial equivalence of performance between Neuro Insight V1.0 subject device and Olea Sphere® V3.0 predicate device.

- Intra- and inter-exam co-registration: FLAIR-DWI, FLAIR-DSC, FLAIR-T1, FLAIR-T1g, FLAIR-T2, and FLAIR-follow-up FLAIR.

  Neuro Insight V1.0 was qualitatively assessed by the three US board-certified neuroradiologists using 60 anonymized brain MRI cases. The visual analysis reported that all 6 co-registrations (FLAIR-DWI, FLAIR-DSC, FLAIR-T1, FLAIR-T1g, FLAIR-T2, FLAIR-follow-up FLAIR) provided by Neuro Insight V1.0 subject device were considered as acceptable for reading and interpretation.

Neuro Insight V1.0 subject device has substantially equivalent indications for use, technological characteristics, and principles of operation as Olea Sphere V3.0 predicate device. The minor technological differences between Neuro Insight V1.0 and its predicate device raise no new questions of safety or effectiveness, as the user confirmation feature is included in the reference device which was cleared for the same intended use. The methods for verification and validation testing of the subject device are well-supported in this regulation and by the predicate and reference devices' clearances, and data from such testing demonstrates the device's safety and performance.

Thus, Neuro Insight V1.0 is substantially equivalent to predicate Olea Sphere V3.0.