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

August 25, 2025

Re: K243680
Trade/Device Name: Neurovascular 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 21, 2025
Received: July 21, 2025

Dear John 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,

Jessica Lamb, PhD
Assistant Director
Imaging Software 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)*

K243680

Device Name

Neurovascular Insight V1.0

Indications for Use *(Describe)*

Neurovascular Insight V1.0 is an optional user interface for use on a compatible technical integration environment and designed to be used by trained professionals with medical imaging education including, but not limited to, physicians. Neurovascular Insight V1.0 is intended to:

- Display and, if necessary, export neurological DICOM series and outputs provided by compatible processing docker applications, through the technical integration environment.
- Allow the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided by the technical integration environment as inputs to the docker application to reprocess the outputs. When available, Neurovascular Insight V1.0 display can be updated with the reprocessed outputs.
- If requested by an application, allow the user to confirm information before displaying associated outputs and export them.

The device does not alter the original image information and is not intended to be used as a diagnostic device. The outputs of each compatible application must be interpreted by the predefined intended users, as specified in the application's own labeling. Moreover, the information displayed is intended to be used in conjunction with other patient information and based on professional judgment, to assist the clinician in the medical imaging assessment. It is not intended to be used in lieu of the standard care imaging.

Trained professionals are responsible for viewing the full set of native 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) #: K243680

510(k) Summary

Prepared on: 2025-07-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Olea Medical S.A.S.
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Correspondent Contact	Mr. John J. Smith
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Neurovascular Insight V1.0
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ, N/A

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223532	Olea S.I.A. Neurovascular V1.0	LLZ
K233342	CINA-ASPECTS	POK

Device Description Summary

21 CFR 807.92(a)(4)

Neurovascular Insight V1.0 is an optional user interface for use on a compatible technical integration environment and designed to be used by trained professionals with medical imaging education including, but not limited to, physicians and medical technicians.
It is worth noting that Neurovascular Insight V1.0 is an evolution of the FDA cleared medical device Olea S.I.A. Neurovascular V1.0 (K223532).
Neurovascular Insight V1.0 does not contain any calculation feat ure or any algorithm (deterministic or AI) .

Intended Use/Indications for Use — 21 CFR 807.92(a)(5)

Neurovascular Insight V1.0 is an optional user interface for use on a compatible technical integration environment and designed to be used by trained professionals with medical imaging education including, but not limited to, physicians. Neurovascular Insight V1.0 is intended to:

- Display and, if necessary, export neurological DICOM series and outputs provided by compatible processing docker applications, through the technical integration environment.
- Allow the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided by the technical integration environment as inputs to the docker application to reprocess the outputs. When available, Neurovascular Insight V1.0 display can be updated with the reprocessed outputs.
- If requested by an application, allow the user to confirm information before displaying associated outputs and export them.

The device does not alter the original image information and is not intended to be used as a diagnostic device. The outputs of each compatible application must be interpreted by the predefined intended users, as specified in the application's own labeling. Moreover, the information displayed is intended to be used in conjunction with other patient information and based on professional judgment, to assist the clinician in the medical imaging assessment. It is not intended to be used in lieu of the standard care imaging.

Trained professionals are responsible for viewing the full set of native images per the standard of care.

Indications for Use Comparison — 21 CFR 807.92(a)(5)

Both the subject Neurovascular Insight V1.0 and predicate Olea S.I.A Neurovascular V1.0 are used for the visualization of MR and CT studies and the edition of parameters. Both systems are for use in clinical/hospital environments by any trained professionals.

The minor differences in the indications for use between the two devices are that:

• Neurovascular Insight V1.0 is for use on a compatible technical integration environment, whereas Olea S.I.A Neurovascular V1.0 is solely to be used on the Olea Medical technical integration platform Olea S.I.A. V1.0, which is a specific compatible technical integration environment.
• Neurovascular Insight V1.0 allows the user to confirm information before displaying associated outputs and export them if requested by an application, while Olea S.I.A Neurovascular V1.0 does not. However, this difference in indications for use is largely a reflection of a difference in technological characteristics, which is addressed in the section below.
• Neurovascular Insight V1.0 is intended to be used by trained professionals while Olea S.I.A Neurovascular V1.0 by trained radiologists and surgeons, which are a subset of trained professionals.

Therefore, both devices have substantially equivalent indications for use regarding visualization of MR and CT studies and edition of parameters.

Technological Comparison — 21 CFR 807.92(a)(6)

Both the subject Neurovascular Insight V1.0 and predicate Olea S.I.A. Neurovascular V1.0 have similar technological characteristics as they both provide the same tools:

- MR and CT images loading and visualization
- Standard Viewing tools
- 3D MIP visualization
- Reset layout
- Manual side selection
- Manual AIF/VOF selection
- Dedicated report.

Neurovascular Insight V1.0 and Olea S.I.A. Neurovascular V1.0 have essentially equivalent features. Both are used to view MR and CT images and edit parameters. Note that the modification of both parameters, side selection and AIF/VOF selection, is identically managed in the subject device and in the predicate device.

The minor difference in the technological characteristics between the two devices is that Neurovascular Insight V1.0 allows the user to manually select ASPECTS region and confirm information before displaying associated outputs and export them if requested by an application, while Olea S.I.A Neurovascular V1.0 does not. However, this user feature to confirm outputs is supported by CINA-ASPECTS UI Agent, included in the reference CINA-ASPECTS device which was cleared for the same intended use with this same confirmation feature.

Therefore, this minor difference in the technological characteristics between both devices does not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Olea Medical has conducted validation testing of the Neurovascular Insight V1.0. Internal verification 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.

Neurovascular 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;
• Software validation test.

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

Neurovascular Insight V1.0 provides no output. Therefore, the comparison to predicate was based on the comparison of features available within both devices.

No performance feature requires a qualitative or quantitative comparison and validation. Each feature has been tested during the verification phases of Neurovascular Insight V1.0 as described in the software test description (STD) and successfully performed as reported in the software test report (STR). Specific features highlighted by the risk analysis have been additionally tested during the usability process of Neurovascular Insight V1.0 to consider human factor as mentioned in the use specification (see Appendix 'OM-DP-STK_HMI_MM-10-021-Use specification-V02_AINN'). All tests were executed in accordance with the User Guide and the operators reported no issue, without occurrence of any clinically blocking bug and no incident during processing.

For more details, please refer to Appendix 'OM-DP-STK_HMI_MM-10-018-Comparison and Validation-V02_AINN'.

Neurovascular Insight V1.0 subject device has substantially equivalent indications for use, technological characteristics, and principles of operation as Olea S.I.A Neurovascular V1.0 predicate device. The minor technological difference between Neurovascular 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, Neurovascular Insight V1.0 is substantially equivalent to predicate Olea S.I.A. Neurovascular V1.0.