Olea Medical
℅ John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
Columbia Square 555 Thirteenth Street, NW
WASHINGTON DC 20004

June 6, 2023

Re: K223532
Trade/Device Name: Olea S.I.A. Neurovascular V1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 9, 2023
Received: May 9, 2023

Dear John Smith, M.D., J.D.:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of 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: 06/30/2023
*See PRA Statement below*

510(k) Number *(if known)*
K223532

Device Name

Olea S.I.A. Neurovascular V1.0

Olea S.I.A. Neurovascular V1.0 is an optional user interface for use on the Olea Medical technical integration platform Olea S.I.A. V1.0 and is designed to be used by trained radiologists and surgeons.

Olea S.I.A. Neurovascular V1.0 is intended to:

- display MR and CT series and outputs provided by compatible docker applications processing, through the technical integration platform,
- allow the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided through the technical integration platform as inputs to the docker application to reprocess outputs. When available, Olea S.I.A. Neurovascular V1.0 display can be updated with the reprocessed outputs.

The device does not alter the original image information and is not intended to be used as a diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. 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.

Trained radiologists and surgeons 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.**

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

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**510(k) SUMMARY**

**Olea Medical's Olea S.I.A. Neurovascular V1.0**

**Submitter** K223532

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Date Prepared: November 23, 2022

**Name of Device:** Olea S.I.A. Neurovascular V1.0

**Common or Usual Name:** PACS

**Regulation Name:** Medical Image Management and Processing System

**Regulatory Class:** 21 CFR 892.2050

**Product Code:** LLZ

**Predicate Device:** Olea Sphere V3.0 (K152602)

**Intended Use / Indications for Use**

*Olea S.I.A. Neurovascular V1.0 is an optional user interface for use on the Olea Medical technical integration platform Olea S.I.A. V1.0 and is designed to be used by trained radiologists and surgeons.*

*Olea S.I.A. Neurovascular V1.0 is intended to:*

- *display MR and CT series and outputs provided by compatible docker applications processing, through the technical integration platform,*
- *allow the user to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided through the technical integration platform as inputs to the docker application to reprocess outputs. When available, Olea S.I.A. Neurovascular V1.0 display can be updated with the reprocessed outputs.*

*The device does not alter the original image information and is not intended to be used as a diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. 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.*

*Trained radiologists and surgeons are responsible for viewing the full set of native images per the standard of care.*

**Device Description**

*Introduction*

Olea S.I.A. Neurovascular V1.0 is a visualization solution of docker applications results. It is an interface embedded on Olea S.I.A. V1.0 platform and uses the components of Olea S.I.A. V1.0 platform to display the outputs of docker applications to which it is entirely dedicated.

Olea S.I.A. Neurovascular V1.0 allows the user to visualize native DICOM series and docker applications outputs and to modify parameters that are optional inputs of these applications.

*Olea S.I.A. Neurovascular V1.0 interaction with the Olea S.I.A. technical platform and docker applications*

To be used, Olea S.I.A. Neurovascular V1.0 needs:

- a technical base, which is provided by Olea S.I.A. V1.0 platform; and
- one or more applications installed on the Olea S.I.A. V1.0 platform that provide outputs that can be managed by Olea S.I.A. Neurovascular V1.0.

The technical platform:

- receives outputs from docker applications;
- makes these outputs available to related DICOM viewers. If the docker applications are compatible with Olea S.I.A. Neurovascular V1.0, they are proposed as the default software to visualize the outputs;
- retrieves the modified parameters in Olea S.I.A. Neurovascular V1.0 to be able to relaunch the concerned docker applications with these new input parameters.

Olea S.I.A. Neurovascular V1.0 does not contain any calculation feature or any algorithm (deterministic or AI).

*Olea S.I.A. Neurovascular V1.0 operating principles and technological characteristics*

Olea S.I.A. Neurovascular V1.0 is an interface embedded on Olea S.I.A. V1.0 platform. Olea S.I.A. Neurovascular V1.0 communicates with API that exists on Olea S.I.A. V1.0 platform only. Olea S.I.A. Neurovascular V1.0 is launched via a link to a web browser and a secure connection.

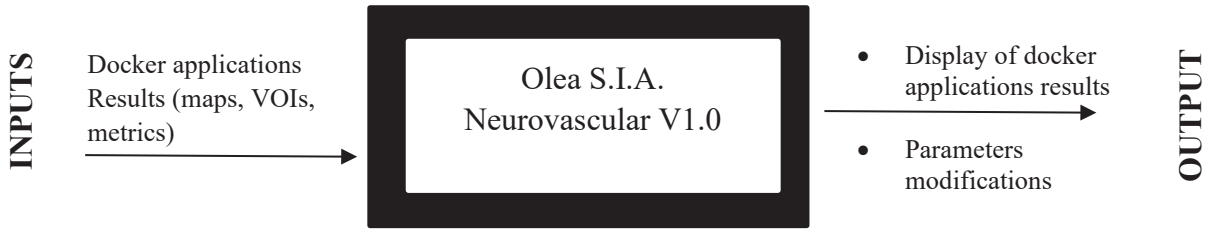


**Figure 5: Olea S.I.A. Neurovascular V1.0 inputs/outputs**

Olea S.I.A. Neurovascular V1.0 receives data coming from docker applications. These data can either be maps, VOIs, or metrics. Olea S.I.A. Neurovascular V1.0 is able to display these results on a dedicated user interface designed in accordance with the clinical need that provides tools to visualize and manipulate images. There is no Olea S.I.A. Neurovascular V1.0 functionality on top of the applications cleared functionalities: the subject device only serves for display of cleared outputs and/or information.

Olea S.I.A. Neurovascular V1.0 also gives the possibility to edit and modify parameters that are optional inputs of aforementioned applications. These modified parameters are provided through the technical integration platform as inputs to the docker application to reprocess outputs. When available, Olea S.I.A. Neurovascular V1.0 display is updated with the reprocessed outputs.

**Substantial Equivalence**

**Table 1: Substantial Equivalence Comparison Table**

| Olea S.I.A Neurovascular V1.0 | Olea Sphere® V3.0 (K152602) |
|---|---|
| MR and CT images visualization including standard viewing tools | YES |
| Manual selection | YES |
| Dedicated Report | YES |

To explain that the subject device and the predicate device are comparable, it is important to point out that Olea S.I.A. Neurovascular V1.0 features represent only a part of the features available in the predicate device Olea Sphere V3.0.

Both systems are used for the visualization and analysis of MR and CT studies. Both systems are for use in hospitals, imaging centers and radiologist reading practices by any trained radiologist or surgeon (part of trained professionals) who may require and is granted access to patient imaging, demographic, and report information.

Both the Olea S.I.A. Neurovascular V1.0 and Olea Sphere V3.0 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.

Olea S.I.A. Neurovascular V1.0 and Olea Sphere V3.0 have essentially equivalent features. The two minor differences are:

- Olea Sphere® V3.0 provides both viewing and processing capabilities while Olea S.I.A. Neurovascular V1.0 is only for visualization, and
- Olea S.I.A. Neurovascular V1.0 is displayed in a web-browser whereas Olea Sphere's viewer is directly embedded in the software itself.

These minor differences do not impact the intended use of the device or raise different questions of safety and efficacy.

**Performance Data**

Olea Medical has conducted validation testing of the Olea S.I.A. Neurovascular 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.

Olea S.I.A. Neurovascular 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 Olea S.I.A. Neurovascular V1.0 has a safety and effectiveness profile that is similar to the predicate device.

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

**Conclusions**

Olea S.I.A. Neurovascular V1.0 is substantially equivalent to the predicate device, Olea Sphere® V3.0. The Olea S.I.A. Neurovascular V1.0 has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device.

In addition, the minor technological differences between the Olea S.I.A. Neurovascular V1.0 and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the Olea S.I.A. Neurovascular V1.0 is as safe and effective as the Olea Sphere® V3.0. Thus, the Olea S.I.A. Neurovascular V1.0 is substantially equivalent.