July 6, 2022

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

Re: K221426
Trade/Device Name: Functional MR 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 16, 2022
Received: May 16, 2022

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 (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,

for

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: 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)*

K221426

Device Name

Functional MR V1.0

Functional MR V1.0 is an optional image processing software application that is intended for use on Olea Sphere® V3.0 software package.

It is intended to be used by trained professionals including, but not limited to, physicians, MR technicians, radiographers.

Functional MR V1.0 includes a software module that computes the activation map from a BOLD sequence and supports the visualization, analysis of activation maps.

Functional MR V1.0 can also be used to provide reproducible measurements of derived maps. These measurements include thresholds modification and ROI analysis.

Functional MR V1.0 may also be used as an image viewer of multi-modality digital images, including BOLD and DTI images.

When interpreted by a skilled physician, Functional MR V1.0 provides information that may be used in a clinically useful context. Patient management decisions should not be based solely on the results of Functional MR V1.0.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Olea Medical's Functional MR V1.0

Submitter

Olea Medical
93 avenue des Sorbiers, ZI ATHELIA IV
13600, La Ciotat
France
Phone: +33 4 42 71 24 20
Facsimile: +33 4 42 71 24 27
Contact Person: Nathalie Palumbo

Date Prepared: May 16, 2022

Name of Device: Functional MR V1.0

Common or Usual Name: PACS

Classification Name: Medical Image Management and Processing System

Regulatory Class: 21 CFR 892.2050

Product Code: LLZ

Predicate Device

nordicBrainEx v2.3.7,

- Manufacturer: NordicNeurolab AS® (K163324)
- Device Name: nordicBrainEx v2.3.7
- Regulation Number: 21 CFR 892.2050
- Product Code: LLZ

Intended Use / Indications for Use

Functional MR V1.0 is an optional image processing software application that is intended for use on Olea Sphere® V3.0 software package. It is intended to be used by trained professionals including, but not limited to, physicians, MR technicians, radiographers.

Functional MR V1.0 includes a software module that computes the activation map from a BOLD sequence and supports the visualization, analysis of activation maps.

Functional MR V1.0 can also be used to provide reproducible measurements of derived maps. These measurements include thresholds modification and ROI analysis.

Functional MR V1.0 may also be used as an image viewer of multi-modality digital images, including BOLD and DTI images.

When interpreted by a skilled physician, Functional MR V1.0 provides information that may be used in a clinically useful context. Patient management decisions should not be based solely on the results of Functional MR V1.0.

Device Description

Introduction

The functional MRI technique consists of analyzing the blood-oxygen-level dependent (BOLD) contrast images. This is a type of specialized brain and body scan is used to map neural activity in the brain or spinal cord of humans by imaging the change in blood flow (hemodynamic response) related to energy use by brain cells.

Olea Medical proposes the Functional MR V1.0 as an optional medical viewing, analysis and processing, Picture Archiving Communications System (PACS) software module that is intended for use with Olea Sphere® V3.0 software package (K152602). Functional MR V1.0 software application runs on a standard "off-the-shelf" PC workstation.

Functional MR V1.0 interaction with Olea Sphere V3.0

Olea Sphere® V3.0 is the base that handles all communications with outside world (import/export of DICOM files from filesystem or the network, network communications, license checks). As an Olea Sphere V3.0 module, Functional MR V1.0 inherits the cross-functionality of Olea Sphere V3.0. Specifically, Functional MR V1.0 inherits all the visualization functions of Olea Sphere V3.0.

The principle of operation of Functional MR V1.0 is as follows:

- Inputs series (BOLD, T1, T2) are received in Functional MR V1.0 through Olea Sphere V3.0;
- Functional MR V1.0 processes the received series;
- The results of the Functional MR V1.0 processing are provided to Olea Sphere V3.0, which then makes the results available for viewing and to other systems and file systems.

Functional MR V1.0 is used as an image viewer of multi-modality digital images, including BOLD and DTI images. Functional MR V1.0 and DTI are two Olea Sphere V3.0 modules independent but complementary in terms of functionality.

Functional MR V1.0 interface

Functional MR V1.0 module allows the user to choose between two tabs: Basic and Advanced. The basic tab is designed for a quick review of the case (allowing the user to set the threshold (p-value) and select the activation map to display) whereas the Advanced one allows to access and adjust preprocessing parameters and allows the user to analyze the BOLD signal in detail.

Principles of operation of Functional MR V1.0

Functional MR V1.0 is designed for task BOLD sequence analysis and visualization of statistical output maps (neural activation maps).

The BOLD analysis within Functional MR V1.0 includes voxel based statistical analysis using the General Linear Model (GLM) and p- or t-value threshold in order to extract the stimulus related signal.

Following the paradigm configuration associated to each analyzed BOLD sequence, GLM fitting is used to extract derived activation maps.

Based on user-specified paradigm and activated locations in the brain, Functional MR V1.0 is used to compute and display the following features:

- Paradigm display allowing to check and modify the paradigm configuration used for activation map computation. Paradigm configuration is provided through a customizable table and the validated configuration is displayed as colour boxes through a graph where BOLD signal and GLM fitting can be displayed.

- Activation maps which are computed using GLM fitting based on the paradigm configuration set by the user. Activation maps can be filtered by maximizing the correlation of GLM fitted signal with configured paradigm. To do so the user can set a threshold identified as the p-value.

- BOLD signal chart display allowing to display the BOLD signal for specific areas of the analysed BOLD sequence, selected by the user.

- GLM fitting chart display (informing the user on the correlation of the estimated signal with paradigm configuration for specific areas of the analysed BOLD sequence, selected by the user).

- Skull filtering allowing the user to remove specific areas (e.g., background and skull) of the sequence which may not be related to the purpose of the exam.

Functional MR V1.0 can also be used to make measurements of activation maps. These measurements include thresholds modification and ROI analysis.

All the Functional MR V1.0 outputs are made available for Neuro-Navigation systems.

Functional MR V1.0 does not support resting-state BOLD sequences.

When interpreted by a skilled physician, Functional MR V1.0 provides information that may be used in a clinically useful context. Patient management decisions should not be based solely on the results of Functional MR V1.0.

Summary of Technological Characteristics

Functional MR V1.0 is an optional medical viewing, analysis and processing, Picture Archiving Communications System (PACS) software module that is intended for use on Olea Sphere® 3.0 software package.

Both Functional MR V1.0 and nordicBrainEx v2.3.7 are intended to analyze the functional MR data of the brain. Both software applications run on a standard "off-the-shelf" PC workstation and can be used with data and images acquired through DICOM compliant imaging devices and modalities.

Similarly, both devices are for use in hospitals, imaging centers and radiologist reading practices by any trained professional who may require and are granted access to patient image, demographic, and report information. Importantly, neither software product is used for diagnosis. Patient management decisions should not be based solely on the results of either software. Therefore, the intended use of the software is the same.

There are minor differences between the two devices. For example, Functional MR V1.0 is a software application intended to be used on Olea Sphere V3.0 whereas nordicBrainEx v2.3.7 is a standalone software. Functional MR V1.0 is only to be used with the cleared Olea Sphere V3.0 PACS (K152602). The Functional MR V1.0 also allows the computation of “Laterality Index”. However, this feature does not impact the location and detection of neuro-activated areas. Lastly, Functional MR V1.0 allows the application of “Bonferroni Correction” for a better conspicuity of activated area. These two features do not impact on the safety and performance of the application. Therefore, these minor differences do not impact the safety or effectiveness of the subject device.

Performance Data

Olea Medical has conducted extensive validation testing of the Functional MR V1.0 as a PACS software module intended for use with the Olea Sphere V3.0 system, cleared under K152602. Internal verification and validation testing confirms that the product specifications are met.

Functional MR V1.0, as an optional application of the Olea Sphere V3.0 software, 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 main groups of tests performed include:

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

In addition to software performance testing, the company conducted additional validation testing to compare the results of Functional MR V1.0 with the predicate. nordicBrainEx v2.3.7 (NordicNeurolab AS®) was used as a comparison for Functional MR V1.0 to evaluate performance of BOLD sequence analysis and visualization, viewing and measurement tools, 2D MPR and 3D volume rendering visualization, Paradigm selection and edition, Activation maps, Skull Filtering, Automatic Co-registration, Time Intensity Display, Motion Correction, Slice time correction, Spatial Filtering and Threshold adjusting. The result of this comparison demonstrates that Functional MR V1.0 has a safety and effectiveness profile similar to the predicate device.

Conclusions

Functional MR V1.0 is substantially equivalent to the predicate device, nordicBrainEx v2.3.7. The Functional MR V1.0 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device.

In addition, the two minor technological differences between the Functional MR V1.0 and its predicate device raises no new questions of safety or effectiveness. Performance data demonstrate that the Functional MR V1.0 is as safe and effective as nordicBrainEx v2.3.7. Thus, the Functional MR V1.0 is substantially equivalent.

The following Predicate Device Comparison Table provides a summary of the comparison between the Functional MR V1.0 and its predicate device.

Functional MR V1.0	**nordicBrainEx® (K163324)**
Standard image Viewing tools	Yes
Loading, post-processing and exporting of images series in DICOM format	Yes
Measurement tools	Yes
2D MPR visualization	Yes
3D volume rendering visualization	Yes
Paradigm selection and edition	Yes
Activation maps	Yes
Skull Filtering	Yes
Automatic co-registration	Yes
Time Intensity Display	Yes
Motion Correction	Yes
Slice time correction	Yes
Spatial Filtering	Yes
Threshold adjusting	Yes
Makes available as outputs for Neuro-navigation systems	Yes
Laterality Index	N/A
Bonferroni Correction	N/A