DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Olea Medical
% Ms. Caroline Lene
Quality and Regulatory Affairs Manager
93 avenue des Sorbiers, Zone Athelia IV
La Ciotat, 13600
FRANCE

March 3, 2016

Re: K152602
Trade/Device Name: Olea Sphere V3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 11, 2016
Received: February 11, 2016

Dear Ms. Lene:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152602

Device Name
Olea Sphere V3.0

Indications for Use *(Describe)*

Olea Sphere V3.0 is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing, image collage and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere V3.0 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (e.g. dynamic exogenous or endogenous contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast while repeating acquisitions (e.g. over time with or without variable acquisition parameters) where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

Arterial Spin Labeling (ASL) Module - the calculation of parameters related to tissue flow based on a MR technique using the water in arterial blood as endogenous tracer to evaluate the perfusion.

Relaxometry Module – the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate.

Metabolic Module – the calculation of parameters related to the fat fraction based on a MR technique using opposed-phase imaging.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 7 – 510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K 152602

I. Applicant Information

Applicant:

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Date Prepared: **September 9, 2015**

II. Device Identification

Proprietary Name:	**Olea Sphere V3.0**
Common/Usual Name:	PACS
Classification Name:	Picture Archiving Communications System
Regulation Number:	21 CFR 892.2050
Product Codes:	LLZ
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Devices

The **Olea Sphere V3.0** device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

1)

510(k) Number:	**K132095**
Trade Name:	Olea Sphere V2.3
Manufacturer:	Olea Medical
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Classification:	Class II

Additionally, the software architecture of some of the new features introduced in the **Olea Sphere V3.0** is essentially identical to the architecture used by the following FDA cleared predicate devices:

2)

510(k) Number:	**K121434**
Trade Name:	Software Syngo MR D13A for the Magnetom Systems Aera/Skyra/Avanto/Verio
Manufacturer:	Siemens Medical Solutions, Inc.
Classification Name:	System, Nuclear Magnetic Resonance Imaging
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Regulation Number:	21 CFR 892.1000
Product Code:	LNH
Classification:	Class II

3)

510(k) Number:	**K130749**
Trade Name:	Syngo.MR General; Syngo.MR Cardiology; Syngo.MR Vascular
Manufacturer:	Siemens Medical Solutions USA, Inc.
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Classification:	Class II

4)

510(k) Number:	**K141977**
Trade Name:	Magnetom Aera with Software Syngo MR E11A, Magnetom Skyra with Software Syngo MR E11A, Magnetom Skyra with 24 RF Channel
Manufacturer:	Siemens Medical Solutions USA, Inc.
Classification Name:	Class II: Magnetic Resonance Imaging System
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Regulation Number:	21 CFR 892.1000
Product Code:	LNH
Classification:	Class II

IV. Device Description

Olea Sphere V3.0 is a medical viewing, analysis and processing, Picture Archiving Communications System (PACS) software, compliant with the DICOM standard and running on Windows or Linux operating systems.

Olea Sphere V3.0 allows the display, analysis and post-processing of medical images. These images, when interpreted by a trained physician, may yield clinically useful information.

The software provides a wide range of basic image processing and manipulation functions, in addition to comprehensive dynamic image processing and display. The main features of the software are:

- Image Loading & Saving
- Image Viewing
- Image Manipulation
- Image Analysis
- Imaging Processing
- Perfusion post-processing
- Permeability post-processing
- Arterial Spin Labeling (ASL)
- Diffusion-Weighted Imaging (DWI) / Tensor Imaging post-processing (DTI) / Intra-Voxel Incoherent Motion (IVIM)
- Fiber Tracking post-processing
- Collage
- Relaxometry post-processing
- Metabolic post-processing

Depending on the purpose of the imaging, the following optional plug-in are used by the software:

- DWI (for MR imaging)
- DTI (for MR imaging)
- Perfusion (for MR and CT imaging)
- Permeability (for MR and CT imaging)
- Kinetics (for MR imaging)
- ASL (for MR imaging)
- Analysis (for MR and CT imaging)
- Olea Vision (for MR imaging)
- IVIM (for MR imaging)
- Collage (for MR imaging)
- Metabolic (for MR imaging)
- Relaxometry (for MR imaging)

The main users of the program are medical imaging professionals who need to visualize and analyze images acquired primarily with MRI or CT systems. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations

V. Indications for Use Statement

Olea Sphere V3.0 is an image processing software package to be used by trained professionals including, but not limited to, physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing, image collage and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea SphereV3.0 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (e.g., dynamic exogenous or endogenous contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast while repeating acquisitions (e.g., over time with or without variable acquisition parameters) where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

Arterial Spin Labeling (ASL) Module - the calculation of parameters related to tissue flow based on a MR technique using the water in arterial blood as endogenous tracer to evaluate the perfusion.

Relaxometry Module – the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate.

Metabolic Module – the calculation of parameters related to the fat signal fraction based on a MR technique using opposed-phase imaging.

VI. Summary of the Technical Characteristics

Olea Sphere V3.0 is a PACS software designed to access series of MRI and CT images in DICOM format, which can be used to perform image viewing, processing, image collage and analysis of medical images. The system utilizes the information contained in each image meta-data to compare images and to perform zoom, pan and crop functions.

Olea Sphere V3.0 offers a viewing and analysis module that allows to display simultaneously available DICOM image datasets and to save the results into the DICOM database.

Olea Sphere V3.0 offers four types of display for a particular data set:

1. The multi-slice view displays simultaneously all the images of selected series in tabular format where rows represent image series and columns represent cross-sectional levels;

2. The mono-slice view displays simultaneously one image of selected series at a given slice location;

3. The MPR/3D view displays selected series in a 3-dimensional projections; and

4. The follow-up view displays images of series acquired over time.

The system allows the calculation of surfaces and volumes over a set of images by using “segmentation masks”. This also allows the user to optimize selected images by customizing the segmentation masks based on user defined areas and to save the results of this image optimization into PDF format files.

The following **Predicate Devices Comparison Table** provides a summary of the comparison between the **Olea Sphere V3.0** and the predicate devices listed in Section III, with respect to indications for use, environment of use, intended use and limitations of use, principles of operation and performance characteristics.

Predicate Device Comparison Table

Device Name	Subject Device: Olea Sphere V3.0	Predicate #1: (K132095) Olea Sphere (V2.3)	Predicate #2: (K121434) Software Syngo MR D13A for the Magnetom Systems Aera/Skyra/Avanto /Verio	Predicate #3: (K130749) Syngo.MR General; Syngo.MR Cardiology; Syngo.MR Vascular	Predicate #4: (K141977) Magnetom Aera with Software Syngo MR E11A, Magnetom Skyra with Software Syngo MR E11A, Magnetom Skyra with 24 RF Channel	Significant Differences
Product Code	LLZ	LLZ	LNH	LLZ	LNH	The subject device and predicates #1 and #3 are classified as Product Code LLZ under regulation 892.1000, whereas predicates #2 and #4 are classified as Product Code LNH, under regulation 892.1000.
Regulation #	892.2050	892.2050	892.1000	892.2050	892.1000	
Class	II	II	II	II	II	No difference.
Indications for Use	Olea Sphere V3.0 is an image processing software package to	Olea Sphere is an image processing software package to	The Magnetom systems Aera/Skyra/Avanto/	The software comprising the syngo.MR post-	The Magnetom systems [Magnetom Aera and Magnetom	Olea Sphere V3.0 and Olea Sphere V2.3 (predicate #1)

	be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing, image collage and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. Olea SphereV3.0 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a	be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a	Verio with software syngo MR D13A are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the	processing applications are post-processing software/applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the syngc.MR post-processing applications have their own indications for use. Syngo.MR General: is a syngo based post-processing software for viewing, manipulating, and	Skyra] are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when	have essentially an identical Indications for Use, with the exception that Olea Sphere V2.3 does not include ASL, Collage, Relaxometry and Metabolic analysis capabilities (see parts in yellow). With respect to **ASL** analysis, Olea Sphere V3.0 and the Software Syngo MR D13A predicate #2 have substantially equivalent indications for use. With respect to the **Collage** feature Olea Sphere V3.0 and the Syngo.MR General predicate #3 have substantially equivalent indications for use.

	Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (e.g. dynamic exogenous or endogenous contrast enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system. The Dynamic Analysis Module is used for	Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system. The Dynamic Analysis Module is used for	images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis. The Magnetom systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.	evaluating MR images. Syngo.MR Cardiology: is a syngo based post-processing software for viewing, manipulating, and evaluating MR cardiac images. Syngo.MR Vascular: is a syngo based post-processing software for viewing, manipulating, and evaluating MR vascular images.	interpreted by a trained physician, yield information that may assist in diagnosis. The Magnetom systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.	With respect to the **Relaxometry** and **Metabolic** analysis, Olea Sphere V3.0 and Magnetom Aera with Software Syngo MR E11A predicate #4 have substantially equivalent indications for use.

	visualization and analysis of dynamic imaging data, showing properties of changes in contrast while repeating acquisitions (e.g. over time with or without variable acquisition parameters) where such techniques are useful or necessary. This functionality is referred to as: Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to	visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as: Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to				

	extracellular space. Arterial Spin Labeling (ASL) Module - the calculation of parameters related to tissue flow based on a MR technique using the water in arterial blood as endogenous tracer to evaluate the perfusion. Relaxometry Module – the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate. Metabolic Module – the calculation of parameters related to the fat signal fraction based on a MR technique using opposed-phase	extracellular space.				

	imaging.					
Environment of Use	Olea Sphere is for use in hospitals, imaging centers, radiologist reading practices by professional who requires and is granted access to patient image, demographic and report information.	Olea Sphere is for use in hospitals, imaging centers, radiologist reading practices by professional who requires and is granted access to patient image, demographic and report information.	Clinical/Hospital Environment	Clinical/Hospital Environment	Clinical/Hospital Environment	No difference.
Limitations of Use/Intended Use	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Indicated for use as a magnetic resonance diagnostic device (MRDD).	Intended for MR volume data sets.	Indicated for use as a magnetic resonance diagnostic device (MRDD).	No difference. Olea Sphere V3.0 and Olea Sphere V2.3 (predicate #1) have the same limitations of use. The Olea Sphere V3.0 ASL, Collage, Relaxometry and Metabolic analysis features have the same limitation of use (i.e. magnetic resonance imaging) as predicates #2, #3 and #4, respectively.

Principles of Operation	The Olea Sphere software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis (e.g. dynamic	The Olea Sphere software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis (dynamic contrast	It provides both the MR technique acquisition and the map generation post-processing software. *Syngo* ASL (Arterial Spin Labeling) is an MR technique using the water in arterial blood as an endogenous contrast agent to evaluate perfusion non-invasively. *Syngo* ASL provides a robust Pulsed Arterial Spin Labeling sequence which provides in-line calculation of CBF maps from the acquired data.	Syngo.MR Composing (optional) is an offline application for creation of full-format images from overlapping MR volume data sets acquired at multiple stages.	Software Syngo MR E11A for the Magnetom Systems Aera/Skyra offers two new applications, LiverLab (an application of non-invasive liver evaluation) and MyoMaps (an application designed to provide a means to generate pixel maps for myocardial MR relaxation times).	Olea Sphere V3.0 and Olea Sphere V2.3 (predicate #1) have essentially identical principles of operation, with the exception that Olea Sphere V2.3 does not include the ASL, Collage, Relaxometry and Metabolic analysis (see parts in yellow). With respect to the **ASL** analysis, Olea Sphere V3.0 and Software Syngo MR D13A (predicate #2) have substantially equivalent principles of operation, with the minor exception that Olea Sphere V3.0 does not provide the MR acquisition technique, but only

	exogenous or endogenous contrast enhanced imaging data for MRI and CT). DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system. Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic	enhanced imaging data for MRI and CT). DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system. Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic				the map generation post-processing software. With respect to the **Collage** feature Olea Sphere V3.0 and Syngo.MR General (predicate #3) have substantially equivalent principles of operation, with the minor exception that the Olea Sphere V3.0 image composing is not necessarily offline. With respect to the **Relaxometry** and **Metabolic** analysis, Olea Sphere V3.0 and Magnetom Aera with Software Syngo MR E11A (predicate #4) have substantially equivalent principles of operation.

	imaging, showing properties of changes in contrast while repeating acquisitions (e.g. over time with or without variable acquisition parameters) where such techniques are useful or necessary. This functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow	imaging, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow				

	(perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as: Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. This functionality also includes	(perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as: Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.				

	dedicated analysis methods and visualization tools for MR technique using the water in arterial blood as endogeneous tracer to visualize tissue perfusion and evaluate blood flow non-invasively. This functionality is referred to as: Arterial Spin Labeling (ASL) Module - the calculation of parameters related to tissue flow based on a MR technique using the water in arterial blood as endogenous tracer to evaluate the perfusion. This functionality also includes dedicated analysis					

	methods and visualization tools for MR technique using intrinsic tissue properties to visualize and evaluate tissue relaxation times and fat signal fraction. This functionality is referred to as: Relaxometry Module – the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate. Metabolic Module – the calculation of parameters related to the fat signal fraction based on a MR technique using opposed-phase imaging.					

Performance Features	Main software features: • Image Loading & Saving • Image Viewing • Image Manipulation • Image Analysis • Imaging Processing • Perfusion post-processing • Permeability post-processing • Kinetics post-processing • Arterial spin labeling • Diffusion-Weighted Imaging / Tensor Imaging post-processing / Intra-Voxel Incoherent Motion • Fiber Tracking post-processing	Main software features: • Image Loading & Saving; • Image Viewing; • Image Manipulation; • Image Analysis; • Image Processing; • Perfusion Maps; • Permeability Maps; • Diffusion Weighted Imaging/Tensor Imaging Maps; • Fiber Tracking.	Main software features: • Arterial spin labeling	Main software features: • Collage (composing)	Main software features: • Relaxometry post-processing • Metabolic post-processing	Olea Sphere V3.0 performs in a substantially equivalent manner to the Olea Sphere V2.3 (predicate #1), with the exception that Olea Sphere V2.3 does not include the ASL, Collage, Relaxometry and Metabolic features (see parts in yellow). Additionally, Olea Sphere V3.0 enhances the Diffusion Weighted Imaging with the addition of the Intra-Voxel Incoherent Motion analysis. Additionally, Olea Sphere V3.0 includes the Kinetics analysis,

	• Collage (composing) • Relaxometry post-processing • Metabolic post-processing					which is a subset of features already included in the Permeability analysis of Olea Sphere V2.3. With respect to the Olea Sphere V3.0 **ASL, Collage, Relaxometry and Metabolic features**, they perform in a substantially equivalent manner to their respective predicates (predicate #2, #3 and #4).

VII. Summary of Performance Data

Olea Medical has conducted extensive validation testing of the **Olea Sphere V3.0** system, as a PACS that is capable of providing reliable post-processing and display of images for instantaneous multi-parametric analysis. Internal verification and validation testing confirms that the product specifications are met, in support of the substantial equivalence of the intended use and technological characteristic as the predicate devices.

All of the different components of the **Olea Sphere V3.0** software have been stress tested 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 devices.

The main groups of tests performed include:

- Product Risk Assessment
- Software modules verification tests
- Software validation test

VIII. Substantial Equivalence Conclusions

Based on the comparison of intended use, principles of operation and technological characteristics, the **Olea Sphere V3.0** system is substantially equivalent to the Olea Sphere V2.3 software manufactured by Olea Medical (K132095).

Additionally the software architecture of many of the features of the **Olea Sphere V3.0** is essentially identical to the architecture used by other predicates: Software Syngo MR D13A for the Magnetom Systems Aera/Skyra/Avanto/ Verio manufactured by Siemens Medical Solutions, Inc. (K121434), Syngo.MR General; Syngo.MR Cardiology; Syngo.MR Vascular manufactured by Siemens Medical Solutions USA, Inc. (K130749), and Magnetom Aera with Software Syngo MR E11A, Magnetom Skyra with Software Syngo MR E11A, Magnetom Skyra with 24 RF Channel manufactured by Siemens Medical Solutions USA, Inc. (K141977).

The minor technological differences between the **Olea Sphere V3.0** and its predicate devices raise no new issues of safety or effectiveness. The performance and validation data demonstrate that the **Olea Sphere V3.0** is as safe and effective as the predicate devices.