Perspectum Ltd.
% Ioan Wigley
Head of Regulatory Affairs
5520 John Smith Drive
Oxford, Oxfordshire OX4 2LL
United Kingdom

May 19, 2022

Re: K212565
Trade/Device Name: CoverScan v1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 14, 2022
Received: April 15, 2022

Dear Ioan Wigley:

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

Thalia T. Mills, Ph.D.
Director
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)*
K212565

Device Name
CoverScan v1

Indications for Use *(Describe)*
CoverScan is a medical image management and processing software package that allows the display, analysis and post-processing of DICOM compliant medical images and MR data.

CoverScan provides both viewing and analysis capabilities to ascertain quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas and kidney.

CoverScan provides measurements in different organs to be used for the assessment of longitudinal and transversal relaxation time and rate (T1, SR-T1, cT1, T2), fat content (proton density fat fraction or PDFF) and metrics of organ function (e.g., left ventricular ejection fraction and lung fractional area change on deep inspiration).

These metrics derived from the images, when interpreted by a licensed physician, yield information that may assist in diagnosis, clinical management and monitoring of patients.

CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T MRI scanners.

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.

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Date Prepared: 16th of May 2022 K212565

Submitter Details

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Subject and Predicate Device

	Subject Device	Primary Predicate Device	Predicate Device No. 2	Predicate Device No. 3	Predicate Device No. 4
510(k) number	Not known	K152602	K190017	K141480	K101342
Legal Manufacturer	Perspectum Ltd.	Olea Medical	Perspectum Ltd.	Circle	Pixmeo Sarl
Owner/Operator Number	10056574	Not known	10056574	3007301305	3012516536
Device Name	CoverScan v1	Olea Sphere V3.0	Liver*MultiScan* (LMSv3)	Cvi42 v5.11	Osirix MD
Proprietary/Common name	CoverScan	Olea Sphere V3.0	Liver*MultiScan*	Cvi42	Osirix MD v12.0
510k Review Panel	Radiology	Radiology	Radiology	Radiology	Radiology
Regulation Number	892.2050	892.2050	892.1000	892.2050	892.2050
Risk Class	Class II	Class II	Class II	Class II	Class II
Product Class code	LLZ	LLZ	LNH	LLZ	LLZ
Classification	Picture Archiving Communications System	Picture Archiving Communications System	System, Nuclear Magnetic Resonance Imaging	Picture Archiving Communications System	Picture Archiving Communications System

Subject Device Description

Device Description

CoverScan is a post-processing software system comprised of several software modules. It uses acquired MR data to produce metrics of quantified tissue characteristics of the heart, lungs, liver, kidneys, pancreas and spleen.

Metrics produced by CoverScan can be used by licensed physicians in a clinical setting for the purposes of assessing multiple organs.

Intended Use & Indications for Use

CoverScan is a medical image management and processing software package that allows the display, analysis and post-processing of DICOM compliant medical images and MR data.

CoverScan provides both viewing and analysis capabilities to ascertain quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas and kidney.

CoverScan provides measurements in different organs to be used for the assessment of longitudinal and transversal relaxation time and rate (T1, SR-T1, cT1, T2), fat content (proton density fat fraction or PDFF) and metrics of organ function (e.g., left ventricular ejection fraction and lung fractional area change on deep inspiration).

These metrics derived from the images, when interpreted by a licensed physician, yield information that may assist in diagnosis, clinical management and monitoring of patients.

CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T MRI scanners.

Contraindications

CoverScan is indicated for use where MRI is not contraindicated.

Intended Conditions

CoverScan is not intended to be used for use on any specific disease or condition, but the information provided in the report, when interpreted by a licensed physician, may benefit the clinical management, including diagnosis and monitoring of patients.

Standalone Software

CoverScan is a post-processing software device. All operations and features are directly controlled by the CoverScan device. CoverScan does not control other firmware or software outside of the device.

Subject and Predicate Comparison

Subject and Predicate Device Comparison

The following characteristics were compared between the subject device and the predicate devices in order to demonstrate substantial equivalence.

Characteristic	Subject and Predicate Device(s) Comparison				
	CoverScan (Subject device)	Sphere V3.0 (Primary Predicate)	Liver*MultiScan* (LMSv3) **(Predicate Device No. 2)**	Cvi42 **(Predicate Device No. 3)**	Osirix MD **(Predicate Device No. 4)**
Product Code	LLZ	LLZ	LNH	LLZ	LLZ
Regulation Number	892.2050	892.2050	892.1000	892.2050	892.2050
Class	II	II	II	II	II
Intended Use & Indications for Use	CoverScan is a medical image management and processing software package that allows the display, analysis and post-processing of DICOM compliant medical images and MR data.	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.	LiverMultiScan (LMSv3) is indicated for use as a magnetic resonance diagnostic device software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times.	Cvi42 vascular analysis add-on is an image analysis software package add-on for evaluating CT and MR images of blood vessels.	Osirix MD is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Characteristic	Subject and Predicate Device(s) Comparison				
	CoverScan provides both viewing and analysis capabilities to ascertain quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas and kidney.	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 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	LiverMultiScan (LMSv3) is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from compatible MR Systems, to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced.		

Characteristic		Subject and Predicate Device(s) Comparison			
		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.			

Characteristic		Subject and Predicate Device(s) Comparison			
		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.			
	CoverScan provides measurements in different organs to be used for the assessment of fibrosis and/or inflammation of an organ (T1, SR-T1, cT1, T2), fat content (proton density fat fraction or PDFF) and/or some metrics of organ function (e.g., left ventricular ejection fraction and lung fractional area change on deep inspiration).	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.	LiverMultiScan (LMSv3) provides a number of tools, such as automated liver segmentation and region of interest (ROI) placements, to be used for the assessment of selected regions of an image. Quantitative assessment of selected regions include the determination of triglyceride fat fraction in the liver (PDFF), T2* and iron-corrected T1 (cT1) measurements. PDFF may optionally be computed using the LMS IDEAL or three-point Dixon methodology.	Combining digital image process and visualisation tools such as multiplanar reconstruction (MRP)|, thin/thick maximum intensity projection (MIP) thin and thick, inverted thin and thick, volume rendering technique (VRT), curved planner reformation, processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centreline calculation, lumen calculation stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software	

Characteristic			Subject and Predicate Device(s) Comparison		
				package is designed to support the physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesion.	
	These metrics derived from the images, when interpreted by a licensed physician, yield information that may assist in diagnosis, clinical management and monitoring of patients.		These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis.	It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. Cvi42 is a software application that can be used as a stand-alone product or in a networked environment. The target population for the cvi42 is not restricted, however, image acquisition by a cardiac CT or MR scanner may limit the use	Lossy compressed mammographic images and digitised film screen images must not be viewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM “for presentation” images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the users responsibility to ensure monitor quality, ambient light conditions, and image compression

Characteristic	Subject and Predicate Device(s) Comparison				
	CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T MRI scanners.			of the device for certain sectors of the general public.	ratios are consistent with the clinical application.
Limitations of Use	Indicated where MRI is not contraindicated.	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Indicated where MRI is not contraindicated.	Patients suitable to undergo an MRI or CT scan not contra-indicated for MRI or CT.	Lossy compressed mammographic images and digitised film screen images must not be viewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the users responsibility to ensure monitor quality, ambient light conditions, and image compression

Characteristic	Subject and Predicate Device(s) Comparison				
					ratios are consistent with the clinical application.
Device Users	Trained Perspectum internal operators.	The main users of the program are medical imaging professionals who need to visualize and analyse images acquired primarily with MRI or CT systems.	Trained Perspectum internal operator.	Qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images	No restriction on users. Osirix MD is distributed directly from the company website.
Use Environment	Installation of Modules 1-3 of CoverScan are installed on general purpose workstations at Perspectum's image analysis centre by specialist members of staff. Workstations need to meet the minimum technical requirements. Module 4-6 of CoverScan is hosted on Amazon Web Services (AWS) there is no user interface for these modules.	Olea Sphere is for use in hospitals, imaging centres, radiologist reading practices by a professional who requires and is granted access to patient image, demographic and report information.	Installation of LMSv3 is controlled and is installed on general purpose workstations. Workstations need to meet the minimum technical requirements. LMSv3 is installed on workstations at Perspectum's image analysis centre by specialist members of staff.	Cvi42 is a software application that can be used as a stand-alone product or in a networked environment.	Installation of Osirix MD is controlled and is installed on general purpose workstations or in a networked environment. Workstations need to meet the minimum technical requirements.
Clinical Setting	CoverScan is a software device that is intended to be installed on general workstations at	Installed on PC's at the clinical site.	LMSv3 is a standalone software device that is intended to be installed on	Cvi42 is a software application that can be used as a stand-alone	Installation of Osirix MD is controlled and is installed on general

Characteristic	Subject and Predicate Device(s) Comparison				
	Perspectum's image centre. The intended device users will log on to the workstations, access the device, and use the device on general-use HD monitors. CoverScan is a post-processing software, the intended device users are trained Perspectum internal operators. Operators use CoverScan to conduct quantitative analysis of tissue characteristics and function to produce a quantitative report. The end-users for the output from the device, the report, are clinicians who receive and interpret reports.		general use workstations at Perspectum's image analysis centre. The intended device users will log on to the workstations, access the device, and use the device on general-use HD monitors. LMSv3 is a post-processing software, the intended device users are trained Perspectum internal operators. Operators use LMSv3 to conduct quantitative analysis of liver tissue characteristics to produce a report. The end-users for the output from the device, the report, are clinicians who receive and interpret LMSv3 reports.	product or in a networked environment. Cvi42 is a post-processing software, intended device users are qualified medical professionals. Users use may use cvi42 to conduct quantitative analysis to produce a clinical report. The end-users for the output from the device, the report, are clinicians who receive and interpret reports.	purpose workstations or in a networked environment. Osirix MD is a post-processing software. Images and data can be captured, stored, communicated, processed and displayed within the system or in a networked environment. Osirix MD can export DICOM files to CD/DVD or USB sticks, including a stand-alone cross-platform viewer to display the images. It is possible to print directly from DICOM printers images derived from Osirix MD.

Characteristic	Subject and Predicate Device(s) Comparison				
Principles of Operation	CoverScan offers comprehensive functionality for image analysis and visualisation, CoverScan contains multiple modules for the quantitative analysis of tissue characteristics and function. Visualisation and quantification tools for image analysis depend on the module. <u>Module 1 (Liver module)</u> cT1 • Full segmentation of the outer liver contour and liver vasculature of the cT1 parametric map. • ROI placed method on the cT1 map with IQR and median metrics from the placed ROIs potentially across multiple acquired slices.	The Olea Sphere software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analysed 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 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	Allows for the visualisation via parametric maps and quantification of metrics (cT1, T2* and PDFF) from liver tissue and exportation of results & images to a deliverable report. LMSv3 allows for: cT1 • Full segmentation of the outer liver contour and liver vasculature of the cT1 parametric map. IQR and median metrics are reported from the segmentation. • ROI placed method on the cT1 map with IQR and median metrics from the placed ROI's potentially	Cvi42 contains multiple modules for the analysis of blood vessels derived from CT and MR images. Visualisation and quantification tools for image analysis depend on the use case. When used for the analysis of cardiac images the following modules are available:	Osirix MD is a post-processing software. Images and data can be captured, stored, communicated, processed and displayed within the system or in a networked environment.

Characteristic	Subject and Predicate Device(s) Comparison				
	PDFF • Full liver segmentation of the PDFF parametric map where IQR and median metrics are reported from the segmentation. • ROI placed method on the PDFF map with IQR and median metrics from the placed ROIs potentially across multiple acquired slices • PDFF parametric maps are calculated using the LMS IDEAL method (1) <u>Module 2 (Pancreas module)</u> SR-T1 • ROI placed method on the T1 map with IQR and median metrics from the placed ROIs potentially	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 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	across multiple acquired slices. PDFF • Full liver segmentation of the PDFF parametric map where IQR and median metrics are reported from the segmentation. • ROI placed method on the PDFF map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices • PDFF parametric maps are calculated using the LMS IDEAL or DIXON method (1). T2* • ROI placed method on the T2* map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices.		

Characteristic	Subject and Predicate Device(s) Comparison				
	across multiple acquired slices • The calculation of pancreas T1 maps using the MultiScan module uses the signal from supported scanners and MRI field strengths to simulate the data as it would be acquired on the reference scanner, providing improved reproducibility. The SR-T1 pipeline maps MRI-system dependent T1 images to MRI-system independent SR-T1 images and that allows comparison of SR-T1 values over a wide variety of MRI systems PDFF • ROI placed method on the PDFF map with IQR and median metrics from the placed ROIs potentially	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	• T2* parametric maps are calculated from the DIXON method (2)		

Characteristic	Subject and Predicate Device(s) Comparison				
	across multiple acquired slices • PDFF parametric maps are calculated using the LMS IDEAL method (1) <u>Module 3 (Kidney module)</u> T1 • ROI placed method on the T1 map with IQR and median metrics from the placed ROIs potentially across multiple acquired slices	intravascular to extracellular space. This functionality also includes dedicated analysis methods and visualization tools for MR technique using the water in arterial blood as endogenous tracer to visualize tissue perfusion and evaluate blood flow non-invasively. This functionality is referred to as: Arterial Spin Labelling (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:			

Characteristic			Subject and Predicate Device(s) Comparison		
		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.			
	Module 4 (Cardiac function module) Operators may use modules within CoverScan to analyse and quantify cardiac images with the below capabilities: Left Ventricular function • Ejection fraction • End Diastolic Volume – left ventricle • End Systolic Volume – left ventricle • Stroke Volume • Left Ventricle Muscle Mass			Short Axis 3D Module Left Ventricular function • Ejection fraction • End Diastolic Volume – left ventricle • End Systolic Volume – left ventricle • Stroke Volume • Left Ventricle Muscle Mass • Left Ventricular Wall Thickness • Global and regional LV function and volume analysis	

Characteristic	Subject and Predicate Device(s) Comparison				
	• Left Ventricular Wall Thickness T1 mapping Module Assessment of native T1 Relaxation times T1, T1*and R^2 maps with customizable color LUT and polar map display T2 Mapping Module Assessment of segmental T2 times. Module 5 (Lung) Basic calculations to determine the percentage			• Global RV function analysis T1 mapping Module • Assessment of native and post contrast T_1 Relaxation times T1, T1*and R^2 maps with customizable colour LUT and polar map display • Assessment of ECV % per slice and segment including polar map display and map generation with customizable colour LUT T2 Mapping Module Global and Regional Segmental T2 times	Viewing • Zooming, rotating, panning and scrolling

Characteristic			Subject and Predicate Device(s) Comparison		
	change in area from inspiration to expiration from datasets exported from analysis conducted in Osirix MD.				• ROI (Region-Of-Interests) tools are available to measure angles, surfaces, distances, densities, SUV, Cobb angle, volumes • Extract statistical data on 2D or 3D ROI • Image fusion for reviewing PET-CT, PET-MR and SPECT-CT • Ejection Fraction calculation, Growing Region tool Post-processing • 3D rendering tools, such as Multiplanar Reconstructions, Curved Reconstructions, 3D Volume Rendering, 3D Surface Rendering • 3D sculpting tools • Measure distance in 3D Volume Rendering, 3D Curved-MPR or 3D Orthogonal MultiPlanar

Characteristic	Subject and Predicate Device(s) Comparison				
					• 3D rigid registration Post-processing techniques such as MPR (Multiplanar Reconstruction), 3D Rendering (MIP, Volume Rendering and Surface Rendering).
	<u>Module 6 (Metric consolidation)</u> A compiled clinical report containing metrics from modules 1-5, rounding of these numbers along with a reference range.			<u>Reporting Module</u> • Viewing of compiled clinical report • Send and/or save report	
Performance Features	Main software features: • Post-processing, display and allow manipulation of medical MR images • Image loading and saving • Session file loading and saving • Image viewing • Image manipulation • Image analysis • Image processing	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 labelling	Main software features: • Image loading and saving • Session file loading and saving • Image viewing • Image manipulation • Image analysis • Image processing • Relaxometry post-processing	Main software features: • Receive, store, transmit, post process, display and allow manipulation of medical MR and CT images • Clinical server functionality • Visualisation in 2D, 3D and 4D of single or multiple datasets	Main software features: • Image Loading & Saving • Image Viewing • Image Manipulation • Image Analysis • Imaging Processing

Characteristic	Subject and Predicate Device(s) Comparison				
	• Relaxometry post-processing • Fat fraction post-processing • Segmentation of regions of interest	• Diffusion Weighted Imaging / Tensor Imaging postprocessing /Intra-Voxel • Incoherent Motion • Fiber Tracking post-processing • Collage (composing) • Relaxometry post-processing • Metabolic postprocessing	• Fat-fraction post-processing • Segmentation of regions of interest	• Define and edit paths through structures such as centrelines • Analysis of cross references of structures • Fly-through visualisation • Segmentation of regions of interest • Quantitative analysis including, distance, angle, volume, histogram, and tracking quantities over time • Derive metadata or new images from input image sets • Creating/forwarding DICOM images • DICOM compliant	
Design: MR Relaxometry	Relaxometry post-processing (T1, T2 and T2*), and subsequently cT1 and SR-T1.	Relaxometry (for MR imaging) - the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate.	Relaxometry post-processing (cT1 and T2*)	Relaxometry post-processing (T1*, T1 and T2)	N/A
Design: Liver Fat Quantification	Fat fraction postprocessing (PDFF)	Metabolic (for MR imaging) - the calculation of parameters related to the fat signal fraction based on a MR	Fat fraction post-processing (PDFF)	N/A	N/A

Characteristic	Subject and Predicate Device(s) Comparison				
		technique using opposed-phase imaging (otherwise known as PDFF).			
Design: Parametric Maps	An operator can use modules 1-3 of CoverScan to generate T2*, T2 and T1 relaxometry maps fitted from an appropriate set of MR Inversion Recovery images which are Gradient Echo (GRE) and MOLLI acquisition protocols respectively. Modules within CoverScan may also be used to generate fat signal fraction (PDFF) maps calculated from an appropriate set of MR GRE images using the IDEAL (iterative decomposition of water and fat with echo asymmetric and least-squares estimation) methodology (13). Module 5 within CoverScan can be used to calculate percentage change in area from inspiration to expiration	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. Depending on the purpose of the imaging, the following optional plug-in are used by the software: • Metabolic (for MR imaging) - the calculation of parameters related to the fat signal fraction based on a MR technique	An operator can use LMSv3 to generate T1 maps fitted from an appropriate set of MR Inversion Recovery images which are Gradient Echo (GRE) and MOLLI acquisition protocols, acquired from supported MR Systems. The T1 mapping uses a model of MR physics shown in (3). Multiple image signal measurements are for a number of different inversion times. Fitting the model to these measurements on a pixel-by-pixel basis allows an estimation of the pixel-wise T1 values. The three-parameter model fitting is performed using a Nelder-Mead Simplex algorithm (4). LMSv3 utilizes magnetic resonance images that exploit	Cvi42 can be used to receive, store, transmit, post process, display and allow manipulation of medical MR and CT images. An operator may use cvi42 to generate T1 maps fitted from an appropriate set of) acquisition protocols, acquired from MR and CT Systems. Depending on the purpose of the imaging, the following optional plug-in can be used in the software:	Osirix MD is a post-processing software. Images and data can be captured, stored, communicated, processed and displayed. Image maps may be processed using the following tools and capabilities: Post-processing • 3D rendering tools, such as Multiplanar Reconstructions,

Characteristic	Subject and Predicate Device(s) Comparison				
	change using the interface that offers tools: • 3D rendering tools, such as Multiplanar Reconstructions, Curved Reconstructions, 3D Volume Rendering, 3D Surface Rendering, 3D Endoscopy • 3D sculpting tools • Measure distance in 3D Volume Rendering, 3D Curved-MPR or 3D Orthogonal MultiPlanar • 3D rigid registration Module 4 within CoverScan can be used to analyse and calculate cardiac metrics to report: Left Ventricular function • Ejection fraction • End Diastolic Volume – left ventricle • End Systolic Volume – left ventricle	using opposed-phase imaging. • Relaxometry (for MR imaging) - the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate.	the difference in resonance frequencies between Hydrogen nuclei in water and triglyceride fat. An operator can use LMSv3 to generate PDFF maps calculated from an appropriate set of MR GRE images using the IDEAL (iterative decomposition of water and fat with echo asymmetric and least-squares estimation) or three-point DIXON methodology (13). Iron corrected T1 (cT1), T2* and Proton Density Fat Fraction (PDFF) parametric maps can be created from all supported scanners. It is possible to use the T2* and PDFF maps and knowledge of the T2* measurements and the scanner field strength to correct for signal changes	Short Axis 3D Module Left Ventricular function • Ejection fraction • End Diastolic Volume – left ventricle • End Systolic Volume – left ventricle • Stroke Volume • Left Ventricle Muscle Mass	Curved Reconstructions, 3D Volume Rendering, 3D Surface Rendering, 3D Endoscopy • 3D sculpting tools • Measure distance in 3D Volume Rendering, 3D Curved-MPR or 3D Orthogonal MultiPlanar • 3D rigid registration • Post-processing techniques such as MPR (Multiplanar Reconstruction), 3D Rendering (MIP, Volume Rendering and Surface Rendering).

Characteristic	Subject and Predicate Device(s) Comparison				
	• Stroke Volume • Left Ventricle Muscle Mass • Maximum Left Ventricular Wall Thickness • Regional segmental T1 times • Regional Segmental T2 times <u>T2 Mapping Module</u> Segmental T2 times		related to iron deposits, producing a cT1 map. The cT1 map eliminates the effects of elevated iron from the T1 measurement (4) PDFF is quantified using the LMS IDEAL or DIXON method. Parametric maps of T2* is computed using the DIXON method.	• Left Ventricular Wall Thickness • Global and regional LV function and volume analysis • Global RV function analysis <u>T1 mapping Module</u> • Assessment of native and post contrast T1 Relaxation times T1, T1* and R^2 maps with customizable colour LUT and polar map display • Assessment of ECV % per slice and segment including polar map display and map generation with customizable colour LUT <u>T2 Mapping Module</u> Global and Regional Segmental T2 times	
Design: Visualisation	Offers numerous views within modules 1-5 of the CoverScan interface can be used to assist	Offers numerous views, dependent on the purpose of the imaging, in the interface	Offers numerous views within the LMSv3 interface can be used to assist in analysis, Iron-	Offers numerous views, dependant on the purpose of the imaging, in the	Osirix MD offers the 2D, 3D and 4D viewing of medical images read

Characteristic	Subject and Predicate Device(s) Comparison				
	in analysis, T1, T2* and Proton Density Fat Fraction (PDFF)) parametric maps can be created from all supported scanners. R^2 maps can also be utilised to assess the quality of the map fitting. Colormaps in the parametric maps are designed to have maximum contrast on organ tissue.	that can be used to assist in analysis of relaxometry and metabolic post-processing.	corrected T1 (cT1), T2* and Proton Density Fat Fraction (PDFF)) parametric maps can be created from all supported scanners. R^2 maps can also be utilised to assess the quality of the map fitting. Iron-corrected T1 (cT1) displayed using LMSv3 colormap, designed to have maximum contrast on liver parenchymal tissue.	interface that can be used to receive, store, transmit, post process, display and allow manipulation of medical MR and CT images. The interface allows for the visualisation in 2D, 3D and 4D of single or multiple datasets.	from all types of DICOM files, produced by medical imaging modalities, including images produced by scanners, MRI, ultrasounds, or standard X-rays.
Design: Outputted data	Quantified metrics and images derived from the analysis of tissue characteristics and organ function from parametric maps that are collated into a report for evaluation and interpretation by a licensed physician. Quantification is based on the placement of ROI's (during analysis in Modules 1-3), for each metric. The median and IQR are given as well as a 'reference range'.	Information not given.	Quantified metrics and images derived from the analysis of liver tissue characteristic on parametric maps are collated into a report for evaluation and interpretation by a clinician. When segmentation analysis is used a representative pie chart is provided based on the confirmed segmentation contour from the PDFF map. The voxels within the segmentation are separated	Quantified metrics and images derived from the analysis are collated into a report for evaluation and interpretation by a clinician.	Osirix MD can export DICOM files to CD/DVD or USB sticks, including a stand-alone cross-platform viewer to display the images. It is possible to print directly from DICOM printers images derived from Osirix MD.

Characteristic	Subject and Predicate Device(s) Comparison				
			into 5 categories (<5% PDFF, 5-10% PDFF, 10-33% PDFF, 33-66% PDFF and >66%) to give proportions based on PDFF. These categories were chosen based on the work of Kleiner et al (3) and Satkunasingham et al (4) on the grading of histological features presented in Non-Alcoholic Fatty Liver Disease. Based on the placed ROI's, for each metric the median and IQR are given as well as a 'reference range'.		
Design: Supported Modalities	DICOM 3.0 compliant MR data from supported MRI scanners.	Supports compliant data from both CT and MRI.	DICOM 3.0 compliant MR data from supported MRI scanners.	Supports compliant data from both CT and MRI.	Supports all types of DICOM files, produced by medical imaging modalities, including images produced by scanners, MRI, ultrasounds, or standard X-rays.

Characteristic	Subject and Predicate Device(s) Comparison				
Performance Testing	Perspectum has conducted extensive validation testing of CoverScan, a medical image management and processing system (MIMPS), that is capable of providing reliable post-processing and display of images for multi-parametric analysis. Internal verification and validation testing confirms that the product specifications are met. All of the different components of the CoverScan 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.	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.	Internal verification and validation testing confirms that the product specifications are met. All of the different components of the LMSv3 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.	Not given	Not given

Characteristic	Subject and Predicate Device(s) Comparison				
	The main groups of tests performed include: • Product Risk Assessment • Software modules verification tests • Software validation test Device performance was assessed with purpose-built phantoms and in-vivo acquired data from volunteers covering a range of physiological values for cT1, T1 and PDFF.	The main groups of tests performed include: • Product Risk Assessment • Software modules verification tests • Software validation test	The main groups of tests performed include: • Product Risk Assessment • Software modules verification tests • Software validation test Device performance was assessed with purpose-built phantoms and in-vivo acquired data from volunteers covering a range of physiological values for cT1, T2* and PDFF.		
Human Factors	Assessed in accordance with IEC 62366 and FDA guidance document 'Applying Human Factors and Usability Engineering to Medical Devices.'	Not known	Assessed in accordance with IEC 62366 and FDA guidance document 'Applying Human Factors and Usability Engineering to Medical Devices.'	Not known	Not known
Standards	IEC 62304, IEC 62366, DICOM 3.0, ISO 14971, ISO 13485	Not known	IEC 62304, IEC 62366, DICOM 3.0, ISO 14971, ISO 13485	Not known	Not known

Characteristic	Subject and Predicate Device(s) Comparison				
System/Operating System	Mac OS	Windows or Linux	Mac OS	Windows or Mac OS	Windows or Mac OS
Materials	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Energy Source	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Biocompatibility	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Sterility	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Electrical Safety	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Thermal Safety	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Mechanical Safety	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Radiation Safety	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software
Chemical Safety	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software	Not applicable, post-processing software

In conclusion, the subject device does not result in any new potential safety risk when compared to the chosen predicate device and it performs in accordance with its use characteristics and intended use.

Software and Performance Testing

All product specifications were verified and the overall ability of the product to meet user needs was validated. Testing was performed according to internal company procedures. Software testing and validation were conducted according to written test protocols established before testing was conducted. Software verification and validation testing were conducted, and documentation was provided as detailed in FDA's Guidance for Industry and FDA Staff: "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices." The software level of concern for CoverScan v1 is Moderate, as per FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This device does not control a life supporting or life-sustaining device, nor does it control the delivery of a potentially harmful energy. This device does not control the delivery of treatment, and it does not provide diagnostic information, nor does it provide any vital signs monitoring. The hazard analysis identifies the potential software-related risks of using the device, and the mitigations implemented.

Bench testing included functional verification to ensure software installation, licensing, labeling, and feature functionality all met design requirements. The accuracy and precision of device measurements was assessed using purpose-built phantoms containing vials with different relaxation times corresponding to the physiological ranges of tissue values expected to be seen in-vivo. To assess the precision of CoverScan v1 measurements across supported scanners, in-vivo volunteer data was used. Volunteers participating in the performance testing were representative of the intended patient population. Inter and intra operator variability was also assessed.

CoverScan v1 underwent performance testing under controlled conditions to corroborate that it is safe and effective when used as intended. The performance testing conducted demonstrates that CoverScan v1 is at least as safe and effective as the predicate devices.

Conclusion

CoverScan v1 has the same intended use and similar technological characteristics as the primary predicate's devices, Olea Sphere v3.0. CoverScan is comprised of several modules for the multi-organ quantification of metrics derived from tissue and organ characteristics. Additionally, further predicates are used (LiverMultiScan manufactured by Perspectum Ltd, Osirix MD manufactured by Pixmeo SARL, cvi42 manufactured by Circle Cardiovascular Imaging Inc) to corroborate those differences between the devices do not result in a new intended use for CoverScan and do not raise any questions of safety and effectiveness. It can be concluded that CoverScan is substantially equivalent to the listed predicate devices.

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