March 3, 2023

Perspectum Ltd.
% Ioan Wigley
Head of Regulatory Affairs
Gemini One
5220 John Smith Drive
Oxford, Oxfordshire OX4 2LL
United Kingdom

Re: K230294
Trade/Device Name: CoverScan (CoverScan v1.1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 28, 2022
Received: February 2, 2023

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: 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.

Submission Number *(if known)*

K230294

Device Name

CoverScan (CoverScan v1.1)

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 (T1, srT1, 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 and Siemens 3T 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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K230294

Date Prepared: 28 November 2022

Submitter Details

Owner Address: Perspectum Ltd
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Oxford,
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Contact Person: Ioan Wigley

Subject and Predicate Device

	Predicate Device	Subject Device
510(k) number	K212565	Unknown
Legal Manufacturer	Perspectum Ltd.	Perspectum Ltd.
Owner/Operator Number	10056574	10056574
Device Name	CoverScan v1.0	CoverScan v1.1
Proprietary/Common name	CoverScan	CoverScan
510k Review Panel	Radiology	Radiology
Regulation Number	892.2050	892.2050
Risk Class	Class II	Class II
Product Class code	LLZ	LLZ
Classification	System, Image Processing, Radiological	System, Image Processing, Radiological

Device Name

Device Trade Name	Common Name
CoverScan v1.1	CoverScan, CoverScan v1

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 healthcare professionals (HCPs) in a clinical setting for the purposes of assessing multiple organs.

CoverScan v1.1 is a new version of CoverScan that supports the use of Siemens 3T scan data to enable more scan sites to utilise CoverScan.

Intended 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 (T1, srT1, 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.

Indications for use

CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T and 3T MRI scanners.

Substantial equivalence

The modified CoverScan v1.1 device has the following similarities to the previously cleared CoverScan v1 device.

Characteristic	Subject and Predicate Device Comparison	
	CoverScan v1.0 (Predicate device)	CoverScan v1.1 (Subject Device)
Product Code	LLZ	LLZ
Regulation Number	892.2050	892.2050
Class	II	II

Intended Use & Indications for Use	CoverScan is a medical image management and processing software package that allows the display, analysis and postprocessing 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 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 (T1, srT1, 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.
Indications for use	CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T MRI scanners	CoverScan is not intended for asymptomatic screening. This device is intended for use with Siemens 1.5T **and Siemens 3T** MRI scanners.
The Subject device underwent additional performance testing to show that the performance was the same as the predicate.		
Limitations of Use	Indicated where MRI is not contraindicated.	Same as predicate
Device Users	Trained Perspectum internal operators.	Same as predicate
Use Environment	Installation of Modules 1-5 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.	Same as predicate.

	Module 6 of CoverScan is hosted on Amazon Web Services (AWS) there is no user interface for these modules.	
Clinical Setting	CoverScan is a software device that is intended to be installed on general workstations at 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.	Same as predicate
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.	Same as predicate
	<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. 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	Same as predicate

	PDFF parametric maps are calculated using the LMS IDEAL method **(1)**	
	Module 2 (Pancreas module) sT1 ROI placed method on the T1 map with IQR and median metrics from the placed ROIs potentially across multiple acquired slices PDFF 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)**	Same as predicate
	Module 3 (Kidney module) T1 ROI placed method on the T1 map with IQR and median metrics from the placed ROIs potentially across multiple acquired slices	Same as predicate
	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	Same as predicate

	Stroke Volume Left Ventricle Muscle Mass 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 T_1 Relaxation times T1, T1*and R2 maps with customizable color LUT and polar map display Assessment of ECV % per slice and segment including polar map display and map generation with customizable color LUT <u>T2 Mapping Module</u> Global and Regional Segmental T2 times	
	<u>Module 5 (Lung)</u> Basic calculations to determine the percentage change in area from inspiration to expiration from datasets exported from analysis conducted in Osirix MD.	Same as predicate
	<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. Basic logic algorithm applied to determine if there is evidence of heart impairment from cardiac metrics exported from analysis conducted.	Same as predicate
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 Relaxometry post-processing Fat fraction postprocessing Segmentation of regions of interest	Same as predicate

Design: MR Relaxometry	Relaxometry post-processing (T1, T2 and T2*). And subsequently cT1 and sT1.	Same as predicate
Design: Liver Fat Quantification	Fat fraction postprocessing (PDFF)	Same as predicate
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 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 Stroke Volume Left Ventricle Muscle Mass Left Ventricular Wall Thickness Global and regional LV function and volume analysis Global RV function analysis Assessment of native and post contrast T1 Relaxation times T1, T1* and R2	Same as predicate

	Assessment of ECV % per slice and segment Global and Regional Segmental T2 times	
Design: Visualisation	Offers numerous views within modules 1-5 of the CoverScan interface can be used to assist in analysis, T1, T2* and Proton Density Fat Fraction (PDFF)) parametric maps can be created from all supported scanners. R2 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.	Same as predicate
Design: Outputted data	Quantified metrics and images derived from the analysis of liver tissue characteristic on parametric maps are collated into a datafile that may subsequently be assembled into a report for evaluation and interpretation by a clinician. Based on the placed ROI's (during analysis in Modules 1-3), for each metric the median and IQR are given as well as a 'reference range'.	Same as predicate
Design: Supported Modalities	DICOM 3.0 compliant MR data from supported MRI scanners.	Same as predicate

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 instantaneous 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. 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 sT1, cT1, T1 and PDFF.	Same as predicate
Human Factors	Assessed in accordance with IEC 62366 and FDA guidance document 'Applying Human Factors and Usability Engineering to Medical Devices'	Same as predicate
Standards	IEC 62304, IEC 62366, DICOM 3.0, ISO 14971, ISO 13485	Same as predicate
System/Operating System	Mac OS	Same as predicate
Materials	Not applicable, post-processing software	Not applicable, post-processing software
Energy Source	Not applicable, post-processing software	Not applicable, post-processing software

Biocompatibility	Not applicable, post-processing software	Not applicable, post-processing software
Sterility	Not applicable, post-processing software	Not applicable, post-processing software
Electrical Safety	Not applicable, post-processing software	Not applicable, post-processing software
Thermal Safety	Not applicable, post-processing software	Not applicable, post-processing software
Mechanical Safety	Not applicable, post-processing software	Not applicable, post-processing software
Radiation Safety	Not applicable, post-processing software	Not applicable, post-processing software
Chemical Safety	Not applicable, post-processing software	Not applicable, post-processing software

The change to add the Siemens 3T Scan data was made and performance testing using well established methods demonstrated equal performance between the subject and the predicate. In summary, CoverScan v1.1 is substantially equivalent to the predicate device CoverScan v1.0 (K212565).

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. Based upon comparison of devices and performance testing results CoverScan v1.1 is substantially equivalent to the listed predicate device.