October 2, 2024

Perspectum Ltd
Bhaskar Chikkanna
Director of Regulatory Affairs
Gemini One,
5520 John Smith Drive
Oxford, OX4 2LL
United Kingdom

Re: K241925
Trade/Device Name: VitruvianScan (v1.0)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: September 11, 2024
Received: September 11, 2024

Dear Bhaskar Chikkanna:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241925

Device Name

VitruvianScan (v1.0)

Indications for Use *(Describe)*

VitruvianScan is indicated for use as a magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation that enables the generation, display and review of magnetic resonance medical image data.

VitruvianScan produces quantified metrics and composite images from magnetic resonance medical image data which when interpreted by a trained healthcare professional, yield information that may assist in clinical decisions.

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.

Date Prepared: 25th June 2024

K241925

1 Applicant Details

Applicant Name and Address: Perspectum Ltd
Gemini One,
5520 John Smith Drive,
Oxford Business Park,
Oxford,
OX4 2LL

Owner/Operator Number: 10056574
Establishment Registration Number: 3014232555
Applicant Contact Name: Bhaskar Chikkanna
Applicant Contact Email: bhaskar.chikkanna@perspectum.com
Applicant Contact Phone: +44 (0) 1865 655329

2 Subject and Predicate Device

	Subject Device	Predicate Device	Reference Device
510(k) number	K241925	K211983	K101342
Legal Manufacturer	Perspectum Ltd.	AMRA Medical AB	PIXMEO SARL
Device Trade Name	VitruvianScan (v1.0)	AMRA Profiler	OSIRIX MD
Common Name	Software as a Medical Device	Software as a Medical Device	Picture Archiving Communications System
Panel	Radiology	Radiology	Radiology
Regulation	892.1000	892.1000	892.2050
Risk Class	Class II	Class II	Class II
Product Class code	LNH	LNH	LLZ
Regulation Name	Magnetic Resonance Diagnostic Device	Magnetic Resonance Diagnostic Device	Picture archiving and communications system

3 Subject Device Description

3.1 General Description

VitruvianScan is a standalone, post processing software medical device. VitruvianScan enables the generation, display and review of magnetic resonance (MR) medical image data from a single timepoint (one patient visit).

When a referring healthcare professional requests quantitative analysis using VitruvianScan, relevant images are acquired from patients at MRI scanning clinics and are transferred to the Perspectum portal through established secure gateways. Perspectum trained analysts use the VitruvianScan software medical device to process the MRI images and produce the quantitative metrics and composite images. The device output information is then sent to the healthcare professionals for their clinical use.

The metrics produced by VitruvianScan are intended to provide insight into the composition of muscle and fat of a patient. The device is intended to be used as part of an overall assessment of a patient's health and wellness and should be interpreted whilst considering the device's limitations when reviewing or interpreting images. Therefore, VitruvianScan presents a low level of concern with respect to patient safety since its metrics only augment the clinical information utilized by trained Healthcare Professionals for the management of patients.

VitruvianScan is only used within Perspectum's secure infrastructure by trained analysts to process clinical images and generate metrics. The metrics and composite images output by VitruvianScan are then sent to trained Healthcare Professionals who then utilize these to make clinical decisions in combination with other relevant information obtained from other clinical sources.

3.2 Intended Use

VitruvianScan is a software medical device intended to assist trained healthcare professionals in the non-invasive evaluation of body fat and muscle composition in the general population.

3.3 Indications for Use

VitruvianScan is indicated for use as a magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation that enables the generation, display and review of magnetic resonance medical image data.

VitruvianScan produces quantified metrics and composite images from magnetic resonance medical image data which when interpreted by a trained healthcare professional, yield information that may assist in clinical decisions.

3.4 Intended Patient Population

General population — VitruvianScan has no demographic or population restrictions.

3.5 Contraindications

- None – Software only device

3.6 Warnings/Precautions

- VitruvianScan **must not** be used for direct diagnosis of patients.
- VitruvianScan generated metrics **must** only be interpreted by trained healthcare professionals.
- VitruvianScan output must not be used **on its own** to make any treatment decisions relating to any specific diseases or health conditions.

4 Substantial Equivalence

Table below provides a comparison of attributes between the subject device and the predicate device to demonstrate substantial equivalence. Differences between the devices are commented.

Attributes	**Subject Device**	**Predicate Device**	**Comments**
Device trade name	VitruvianScan	AMRA Profiler	N/A
Manufacturer	Perspectum Ltd	AMRA Medical AB	N/A
510(k) number (if assigned)	TBD	K211983	N/A
Regulation	892.1000	892.1000	No difference
Product Code	LNH	LNH	No difference
Intended use	VitruvianScan is a software medical device	Not defined	Subject device has a separate intended use statement.

	intended to assist trained healthcare professionals in the non-invasive evaluation of body fat and muscle composition in the general population		
Indications for use	VitruvianScan is indicated for use as a magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation that enables the generation, display and review of magnetic resonance medical image data. VitruvianScan produces quantified metrics and composite images from magnetic resonance medical image data which when interpreted by a trained healthcare professional, yield information that may assist in clinical decisions.	Indicated for use as a magnetic resonance diagnostic device software application for non- invasive fat and muscle evaluation that enables the generation, display and review of 2D magnetic resonance medical image data. Designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from compatible MR Systems, to display the internal structure of the body including the liver. Other physical parameters derived from the images may also be produced. Provides a number of quantification tools, such as Region of Interest (ROI) placements, to be used for the assessment of regions of an image to quantify liver tissue characteristics, including the determination of fat fraction in the liver, T2 * and muscle volume. These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis.	Subject device does not quantify liver tissue characteristics, liver fat fraction, T2* and muscle volume. Other than these differences, both the subject device and the predicate device are indicated for non-invasive fat and muscle evaluation.
Intended users	Perspectum trained analysts use the device to analyze MRI data and produce output.	AMRA operators use the device to analyze MRI data and produce results.	Similar users

	Trained healthcare professionals interpret the device output for additional support in their clinical decision pathways.	Trained clinicians interpret the results.	
Application	Health and wellness	Health and wellness	No difference
Anatomy and measurements	Abdomen. Visceral Fat Subcutaneous Fat Muscle Area	Abdomen and Thighs. Visceral Fat Subcutaneous Fat Muscle Fat Muscle Volume Liver Fat	Subject device anatomy and measurements are a subset of the predicate device anatomy and measurements
Target population	General population	Adults	Subject device is intended for all ages who are suitable for MRI scans
Contraindications	None, Software only	None, Software only	No difference
Imaging modality	Magnetic resonance imaging systems	Magnetic resonance imaging systems	No difference
Data format	DICOM 3.0 compliant MR image datasets from compatible MR scanners	DICOM 3.0 compliant MR image datasets from compatible MR scanners	No difference
MRI Scanners	GE, Siemens and Philips	GE, Siemens and Philips	No difference
MR field strength	1.5T and 3T	1.5T and 3T	No difference

5 Software Testing

VitruvianScan is a software medical device. The documentation level evaluation document justifies only basic documentation is applicable to VitruvianScan as per FDA guidance, *Content of Premarket Submissions for Device Software Functions for Industry and Food and Drug Administration Staff Document issued on June 14, 2023.* The device has undergone the following tests and successfully passed the acceptance criteria with no residual anomalies.

a. Unit testing
b. Integration testing
c. Software system verification
d. Software system validation
e. User acceptance tests

6 Performance Testing

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

Scanners Assessed
Siemens 1.5T
Siemens 3T
GE 1.5T
GE 3T
Philips 1.5T

Philips 3T

The performance was tested for the following aspects:

a. Repeatability of metrics for the same subject, on the same manufacturer and field strength, acquired on the same day
b. Reproducibility of metrics for the same subject, on the same manufacturer but a different field strength, acquired on the same day
c. Characterization of inter-operator variability
d. Characterization of intra-operator variability
e. Results from testing using the subject device were compared with the results from testing using reference regulated device 'OSIRIX MD' for benchmarking performance
f. Comparative testing between the operators' results and the gold standard (mean of 3 radiologists results)

All aspects of the performance tests met the defined acceptance criteria, thereby assuring robust clinical performance of the device across different scanners, field strengths and patient characteristics.

7 Conclusion

The subject device and the predicate device have similar indications for use and are meant for the same application in health and wellness. The differences highlighted do not constitute a new intended use, are accompanied by information that demonstrates that the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.