Perspectum LTD
℅ Jaco Jacobs
Chief Compliance Officer
Gemini One, 5520 John Smith Drive
Oxford, Oxfordshire OX4 2LL
UNITED KINGDOM

October 2, 2020

Re: K202170
Trade/Device Name: LiverMultiScan (LMSv4)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: March 13, 2020
Received: August 3, 2020

Dear Jaco Jacobs:

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,

Michael D. O'Hara

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202170

Device Name
LiverMultiScan (LMSv4)

Indications for Use *(Describe)*

LiverMultiScan (LMSv4) 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.

LiverMultiScan (LMSv4) 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.

LiverMultiScan (LMSv4) 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 assessments of selected regions include the determination of triglyceride fat fraction in the liver (PDFF), T2* and iron-corrected T1 (cT1) measurements. T2* may be optionally computed using the DIXON or LMS MOST methods.

These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis

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: 21st of July 2020

1. Submitter Details

Owner Address: Perspectum Ltd
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Oxford Business Park,
Oxford,
OX4 2LL

Owner/Operator Number: 10056574

Establishment Registration Number: 3014232555

Contact Person: Dr Jaco Jacobs
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2. Subject and Predicate Device

	Subject Device	Predicate Device
510(k) number	Not known	K190017
Legal Manufacturer	Perspectum Ltd.	Perspectum Diagnostics Ltd.
Owner/Owner Operator	10056574	10056574
Device Name	LiverMultiScan (LMSv4)	LiverMultiScan (LMSv3)
Proprietary/Common	LiverMultiScan	LiverMultiScan
Panel	Radiology	Radiology
Regulation	892.1000	892.1000
Risk Class	Class II	Class II
Product Class code	LNH	LNH
Classification	System, Nuclear Magnetic Resonance Imaging	System, Nuclear Magnetic Resonance Imaging

3. Subject Device Description

3.1. General

LiverMultiScan is a standalone software device. The purpose of the LiverMultiScan device is to assist a trained operator with the evaluation of information from Magnetic Resonance (MR) images from a single time-point (a patient visit). LiverMultiScan is a post-processing software device, a trained operator uses tools such as automatic liver segmentation and region of interest placement upon previously acquired MR images, from which a summary report is generated. The summary report is subsequently sent to an interpreting clinician at the acquiring site.

LiverMultiScan is not intended to replace the established procedures for the assessment of a patient's liver health by an interpreting clinician, providing many opportunities for competent human intervention in the interpretation of images and information displayed.

The metrics are intended to be used as an additional diagnostic input to provide information to clinicians as part of a wider diagnostic process. It is expected that in the normal course of liver disease diagnosis, patients will present with clinical symptoms or risk factors which may indicate liver disease. The interpreting clinician needs to take into consideration the device's limitations and accuracy during clinical interpretation.

Liver function tests, blood tests, ultrasound scanning as well as liver biopsy are all expected to be used at the discretion of a qualified clinician in addition to information obtained from the use of LiverMultiScan metrics. The purpose of LiverMultiScan metrics is to provide imaging information to assist in characterizing tissue in the liver, in addition to existing methods for obtaining information relating to the liver. LiverMultiScan metrics are not intended to replace any existing diagnostic source of information but can be used to identify patients who may benefit most from further evaluation, including biopsy.

Information gathered through existing diagnostic tests and clinical evaluation of the patient, as well as information obtained from LiverMultiScan metrics, may contribute to a diagnostic decision.

LiverMultiScan is not a computer-aided diagnostic device and can only present imaging information which must be interpreted by a qualified clinician. LiverMultiScan is an aid to diagnosis; and diagnosis and treatment decisions remains the responsibility of the clinician.

In consequence, the product is considered to have no adverse effect on health since the results represent only a part of the information that the user will utilize for final interpretation. In this regard, LiverMultiScan presents a moderate level of concern with respect to patient safety.

3.2. Sterilization and Shelf Life

LMSv4 is a standalone software device thus it is non-contact, non-invasive and non-sterile. The shelf life of LMSv4 is indefinite as long as the manufacturer continues to support the device. Both sterilization and shelf life characteristics are equivalent of the predicate device.

3.3. Biocompatibility

LMSv4 is a standalone software device thus it is non-contact and non-invasive. No biocompatibility testing was deemed necessary to demonstrate the safety and effectiveness of LMSv4. LMSv4 does not consists of materials that differ from the predicate device.

3.4. Software

LMSv4 was successfully validated and verified against the requirements specification and its intended use. The results from the validation and verification activities, documented in this submission, corroborate that LMSv4 meets the product requirement specifications and intended use, which is deemed to be substantially equivalent to the predicate (see section below).

Validation and verification activities were conducted in a controlled environment and in compliance with IEC 62304:2006, ISO 13485:2016 and 21 CFR 820. LMSv4 is also in compliance with the DICOM standard.

3.5. Electromagnetic and Electrical Safety

LMSv4 is a standalone software device, there are no electromagnetic or electrical safety risks associated with the direct use of the LMSv4 device. No electromagnetic or electrical safety testing was deemed necessary to demonstrate the safety and effectiveness of LMSv4.

4. Subject and Predicate Comparison

4.1. Subject and Predicate Device Comparison

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

Comparison of Subject and Predicate Device		
Characteristic	LMSv4 (Subject device)	LMSv3 (Predicate device)
Intended Use and Indications for Use	"LiverMultiScan (LMSv4) 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. LiverMultiScan (LMSv4) 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. LiverMultiScan (LMSv4) 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 assessments of selected regions include the determination of triglyceride fat fraction in the liver (PDFF), T2* and iron-corrected T1 (cT1) measurements. T2* may be optionally computed using the DIXON or LMS MOST methods. These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis."	"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. 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. 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 assessments 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. These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis."
Target Population	Patients suitable to undergo an MRI scan and not contra-indicated for MRI.	Patients suitable to undergo an MRI scan and not contra-indicated for MRI.
Device User	Trained Perspectum operator	Trained Perspectum operator
Report User	An interpreting clinician or healthcare practitioner.	An interpreting clinician or healthcare practitioner.
Device Use Environment	Installation of LMSv4 is controlled and installed on general purpose workstations at Perspectum's image analysis centre, by specialist members of staff.	Installation of LMSv3 is controlled and installed on general purpose workstations at Perspectum's image analysis centre by specialist members of staff.

Comparison of Subject and Predicate Device		
Characteristic	LMSv4 (Subject device)	LMSv3 (Predicate device)
Clinical Setting	LMSv4 is a standalone software device that is intended to be installed on 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. LMSv4 is a post-processing software, the intended device users are trained internal Perspectum operators. Operators use LMS to conduct quantitative analysis of liver tissue characteristics to produce a report. The end-users for the output from the device, the pdf report, are clinicians who receive and interpret LMSv4 reports through the QAS.	LMSv3 is a standalone software device that is intended to be installed on 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 internal Perspectum operators. Operators use LMS to conduct quantitative analysis of liver tissue characteristics to produce a report. The end-users for the output from the device, the pdf report, are clinicians who receive and interpret LMSv3 reports through the QAS.
Anatomical Location	Abdomen, Liver	Abdomen, Liver
Energy Considerations	Software only application. The device, a standalone software application, does not deliver, monitor or depend on energy delivered to or from patients.	Software only application. The device, a standalone software application, does not deliver, monitor or depend on energy delivered to or from patients.
Design: Purpose	LMS is a standalone software application that imports MR data sets encompassing the abdomen, including the liver. Visualisation and display of 2D multi-slice, spin-echo MR data can be analysed, and quantitative metrics of tissue characteristics are then reported. Datasets imported into LMS are DICOM 3.0 compliant, reported metrics are independent of the MRI equipment vendor.	LMS is a standalone software application that imports MR data sets encompassing the abdomen, including the liver. Visualisation and display of 2D multi-slice, spin-echo MR data can be analysed, and quantitative metrics of tissue characteristics are then reported. Datasets imported into LMS are DICOM 3.0 compliant, reported metrics are independent of the MRI equipment vendor.
Design: Tools	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. LMSv4 allows for: cT1 • Full segmentation of the outer liver contour and liver vasculature of the cT1 parametric map. Interquartile Range (IQR) and median metrics are reported from the segmentation.	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. Interquartile Range (IQR) and median metrics are reported from the segmentation.

Comparison of Subject and Predicate Device		
Characteristic	LMSv4 (Subject device)	LMSv3 (Predicate device)
	• ROI placed method on the cT1 map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices. T2* • ROI placed method on the T2* map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices. • T2* parametric maps are calculated from the MOST method or the three-point DIXON method. 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 method [1]	• ROI placed method on the cT1 map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices. T2* • ROI placed method on the T2* map with IQR and median metrics from the placed ROI's potentially across multiple acquired slices. • T2* parametric maps are calculated from the three-point DIXON method. 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 can be calculated using either the LMS IDEAL method [1] or the three-point DIXON method [2]
Design: MR Relaxometry	T1, iron-corrected T1 (cT1) and T2* mapping.	T1, iron-corrected T1 (cT1) and T2* mapping.
Design: Liver Fat Quantification	Utilizes MR images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat using the LMS IDEAL method.	Utilizes MR images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat using either the LMS IDEAL method or three-point DIXON method.
Design: Liver Segmentation	LMSv4 supports automatic multi-slice full liver segmentation of the cT1 and PDFF parametric map, use of this functionality is at the discretion of the operator instead or in combination with the ROI based method. The cT1 segmented liver is presented in colour level window, while the rest of the cT1 image is presented in greyscale level window with ducts and liver vasculature excluded from the segmented volume.	LMSv3 supports automatic multi-slice full liver segmentation of the cT1 and PDFF parametric map, use of this functionality is at the discretion of the operator instead or in combination with the ROI based method. The cT1 segmented liver is presented in colour level window, while the rest of the cT1 image is presented in greyscale level window with ducts and liver vasculature excluded from the segmented volume.

Comparison of Subject and Predicate Device		
Characteristic	LMSv4 (Subject device)	LMSv3 (Predicate device)
Design: Regions of Interest (ROI)	Median and interquartile range measurements created from a cross sectional slice of liver tissue. For each parametric map, statistics from multiple Regions of Interest (ROIs) – potentially placed across multiple slices – are summarised.	Median and interquartile range measurements created from a cross sectional slice of liver tissue. For each parametric map, statistics from multiple Regions of Interest (ROIs) – potentially placed across multiple slices – are summarised.
Design: Parametric Maps	Iron corrected T1 (cT1), T2* and Proton Density Fat Fraction (PDFF) parametric maps can be created from all supported scanners. PDFF is quantified using the LMS IDEAL method. Parametric maps of $T2^*$ may be optionally be computed using either the three-point DIXON method or the LMS MOST method.	Iron corrected T1 (cT1), T2* and Proton Density Fat Fraction (PDFF) parametric maps can be created from all supported scanners. PDFF is quantified using the LMS IDEAL method or the three-point DIXON method.
Design: Visualisation	Numerous views within the LMSv4 interface can be used to assist in analysis, Iron-corrected T1 (cT1), T2* and triglyceride fat (also known as 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 LMSv4 colourmap, designed to have maximum contrast on liver parenchymal tissue.	Numerous views within the LMSv4 interface can be used to assist in analysis, iron corrected T1 (cT1), T2* and triglyceride fat (also known as Proton Density Fat Fraction (PDFF)) parametric maps can be created from all supported scanners. Iron corrected T1 (cT1) displayed using the LMSv3 colourmap, designed to have maximum contrast on liver parenchymal tissue.
Design: Supported Modalities	DICOM 3.0 compliant MR data from supported MRI scanners.	DICOM 3.0 compliant MR data from supported MRI scanners.
Design: Report	Quantified metrics and images derived from the analysis conducted of liver tissue characteristic on parametric maps are collated into a report for evaluation and interpretation by a clinician.	Quantified metrics and images derived from the analysis conducted of liver tissue characteristic on parametric maps are collated into a report for evaluation and interpretation by a clinician.
Compatibility with the environment	Installation of LMSv4 is controlled and is installed on general purpose workstations that meet the minimum technical requirements at Perspectum's image analysis centre by specialist members of staff.	Installation of LMSv3 is controlled and is installed on general purpose workstations that meet the minimum technical requirements at PD's image analysis centre by specialist members of staff.
Performance	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.	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.
Supported MRI Systems	Validated across all listed supported manufacturers and field strengths.	Validated across all listed supported manufacturers and field strengths.
Standards	IEC 62304, IEC 62366, DICOM 3.0, ISO 14971, ISO 13485	IEC 62304, IEC 62366, DICOM 3.0, ISO 14971, ISO 13485

Comparison of Subject and Predicate Device		
Characteristic	LMSv4 (Subject device)	LMSv3 (Predicate device)
System/Operating System	Mac OS	Mac OS
Materials	Not applicable, standalone software.	Not applicable, standalone software.
Biocompatibility	Not applicable, standalone software.	Not applicable, standalone software.
Sterility	Not applicable, standalone software.	Not applicable, standalone software.
Electrical Safety	Not applicable, standalone software.	Not applicable, standalone software.
Mechanical Safety	Not applicable, standalone software.	Not applicable, standalone software.
Chemical Safety	Not applicable, standalone software.	Not applicable, standalone software.
Thermal Safety	Not applicable, standalone software.	Not applicable, standalone software.
Radiation Safety	Not applicable, standalone software.	Not applicable, standalone software.

Table 1. Comparison of similar characteristics between the subject and predicate device.

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

5. Performance Testing

LMSv4 underwent performance testing under controlled conditions to corroborate that it is safe and effective when used as intended. The performance testing conducted demonstrates that LMSv4 is at least as safe and effective as the predicate device and does not introduce any new risks.

5.1. Performance Testing - Bench

The accuracy and precision of device measurements was assessed using purpose-built phantoms containing vials with different relaxation times corresponding to the physiological range of liver tissue values expected to be seen in-vivo. Accuracy was measured by the proximity of quantified LMSv4 values to the gold standard. The results of which are summarized below:

Metric	Accuracy	
	1.5T	3T
cT1	-189.5 to -35.11 ms	-187.0 to -19.12 ms
$T2^*$	-0.68 to 0.64 ms	-0.30 to 0.39 ms
IDEAL PDFF	-3.80 to 6.08%	-1.39 to 5.58%

Table 2. Pooled performance testing - bench

- The MOLLI-based T1 measurement produced by LMSv4 is consistent with the literature-reported underestimation of ground truth T1 using MOLLI techniques [34]
- LMSv4 measurement of $T2^*$ is accurate over the expected physiological range of values
- LMSv4 measurement of PDFF is accurate over the expected physiological range of values

5.2. Performance Testing - Clinical

To assess the precision of LMSv4 measurements across supported scanners in-vivo acquired 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. The results of which are summarized below:

Metric	Repeatability Limits of Agreement	Reproducibility Limits of Agreement
cT1 (ROI)	- 43.25 to 26.77 ms	-103 to 91.8 ms
cT1 (Segmentation)	- 40.75 to 25.02 ms	-102.3 to 93.69 ms
T2* (DIXON)	- 5.21 to 6.01 ms	-1.74 to 0.35 ms
T2* (MOST)	- 3.17 to 3.25 ms	-2.40 to 2.15 ms
IDEAL PDFF (ROI)	-1.48 to 1.42%	-2.88 to 2.53%
IDEAL PDFF (Segmentation)	-1.31 to 1.34 %	-2.94 to 2.53%

Table 3. Pooled performance testing - clinical

- LMSv4 measurements of cT1, T2* and PDFF are highly repeatable
- LMSv4 measurements of cT1, T2* and PDFF are reproducible between scanners and field strengths
- The variation introduced by operator measurements with both ROI placement and segmentation method is well within the prescribed acceptance criteria.

5.3. Clinical Investigation

No clinical investigations or studies were conducted during performance testing of LMSv4.

6. Conclusion

The subject device is substantially equivalent to the predicate device, both regulated under regulation 21 CFR 892.1000. Substantial equivalence is based on the following observations:

- The indications for use and intended uses of both the subject device and predicate device are substantially equivalent.
- The subject and predicate devices are both software applications which facilitate the import and visualization of MR data sets to visualise and enable quantification of physiological characteristics in the liver to provide measurements.
- The subject and predicate devices both support tools and features to derive measurements from MR images and parametric maps of tissue characteristics.
- The subject and predicate device facilitate the creation of a medical report containing the images and analysis output derived from quantification of liver tissue parameters intended to be interpreted by a trained clinician.
- Both the subject and predicate devices are designed to run on general-purpose computing hardware and intended to be used in the same environment.
- Performance testing and risk management demonstrates that the subject device performs at least as safely and effectively as the proposed predicate device and supports the determination of substantial equivalence.

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

References

1. Reeder, S. B. *et al.* Iterative decomposition of water and fat with echo asymmetry and least-squares estimation (IDEAL): Application with fast spin-echo imaging. *Magn. Reson. Med.* **54**, 636–644 (2005).
2. Dixon, W. T. Simple proton spectroscopic imaging. *Radiology* **153**, 189–194 (1984).
3. Piechnik, S. K. *et al.* Shortened Modified Look-Locker Inversion recovery (ShMOLLI) for clinical myocardial T1-mapping at 1.5 and 3 T within a 9 heartbeat breathhold. *J. Cardiovasc. Magn. Reson.* **12**, 69 (2010).
4. Puntmann, V. O. *et al.* Are T1 values to characterize myocardial tissue equivalent between various sequences: comparison of MOLLI, shMOLLI, 3'5-MOLLI and SASHA. *J. Cardiovasc. Magn. Reson.* **15**, E18 (2013).