Perspectum Ltd.
℅ Ioan Wigley
Chief Compliance Officer
5520 John Smith Drive
Oxford, Oxfordshire OX4 2LL
UNITED KINGDOM

January 12, 2021

Re: K203280
Trade/Device Name: Hepatica (Hepatica v1)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: October 1, 2020
Received: November 16, 2020

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203280

Device Name
Hepatica (Hepatica v1)

Indications for Use *(Describe)*
Hepatica (Hepatica v1) is a post-processing medical device software that presents quantified metrics which may contribute to the assessment of a patient's liver health.

Hepatica (Hepatica v1) uses image visualisation and analysis tools to process DICOM 3.0 compliant magnetic resonance image datasets to produce semi-automatic segmented 3D models of the liver based on the work of Couinaud and the Brisbane 2000 terminology. For each identified Couinaud segment, volumetric data is determined and reported.

Hepatica (Hepatica v1) may also report iron corrected-T1 (cT1) and PDFF calculated using the IDEAL method from multi-slice acquisitions, on a per segment basis, over the whole liver. Both metrics present numerical values of different fundamental liver tissue characteristics that can be used as measures of liver tissue health.

Hepatica (Hepatica v1) provides trained clinicians with additional information to evaluate the volume and health of a patient's liver on a segmental basis. It is not intended to replace the established procedures for the assessment of a patient's liver health. However, information gathered through existing diagnostic tests, clinical evaluation of the patient, as well Hepatica (Hepatica v1), may support surgical decision making.

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)

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K203280

Date Prepared: 28th October 2020

1. Submitter Details

Owner Address: Perspectum Ltd
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Owner/Operator Number: 10056574

Establishment Registration Number: 3014232555

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2. Subject and Predicate Device

	Subject Device	Predicate Device
510(k) number	K203280	K202170
Legal Manufacturer	Perspectum Ltd.	Perspectum Ltd.
Owner/Owner Operator	10056574	10056574
Device Name	Hepatica (Hepatica v1)	LiverMultiScan (LMSv4)
Proprietary/Common	Hepatica	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. Intended Use

Hepatica (Hepatica v1) is a post-processing medical device software that presents quantified metrics which may contribute to the assessment of a patient's liver health.

Hepatica (Hepatica v1) uses image visualisation and analysis tools to process DICOM 3.0 compliant magnetic resonance image datasets to produce semi-automatic segmented 3D models of the liver based on the work of Couinaud and the Brisbane 2000 terminology. For each identified Couinaud segment, volumetric data is determined and reported.

Hepatica (Hepatica v1) may also report iron corrected-T1 (cT1) and PDFF calculated using the IDEAL method from multi-slice acquisitions, on a per segment basis, over the whole liver. Both metrics present numerical values of different fundamental liver tissue characteristics that can be used as measures of liver tissue health.

Hepatica (Hepatica v1) provides trained clinicians with additional information to evaluate the volume and health of a patient's liver on a segmental basis. It is not intended to replace the established procedures for the assessment of a patient's liver health. However, information gathered through existing diagnostic tests, clinical evaluation of the patient, as well Hepatica (Hepatica v1), may support surgical decision making.

3.2. Sterilization and Shelf Life

Hepatica v1 is a standalone software device thus it is non-contact, non-invasive and non-sterile. The shelf life of Hepatica v1 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

Hepatica v1 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 Hepatica v1. Hepatica v1 does not consist of materials that differ from the predicate device.

3.4. Software

Hepatica v1 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 Hepatica v1 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. Hepatica v1 is also in compliance with the DICOM standard.

3.5. Electromagnetic and Electrical Safety

Hepatica v1 is a standalone software device- there are no electromagnetic or electrical safety risks associated with the direct use of the Hepatica v1 device. No electromagnetic or electrical safety testing was deemed necessary to demonstrate the safety and effectiveness of Hepatica v1.

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	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
Intended Use and Indications for Use	"Hepatica (Hepatica v1) is a post-processing medical device software that presents quantified metrics which may contribute to the assessment of a patient's liver health. Hepatica (Hepatica v1) uses image visualisation and analysis tools to process DICOM 3.0 compliant magnetic resonance image datasets to produce semi-automatic segmented 3D models of the liver based on the work of Couinaud and the Brisbane 2000 terminology. For each identified Couinaud segment, volumetric data is determined and reported. Hepatica (Hepatica v1) may also report iron corrected-T1 (cT1) and PDFF calculated using the IDEAL method from multi-slice acquisitions, on a per segment basis, over the whole liver. Both metrics present numerical values of different fundamental liver tissue characteristics that can be used as measures of liver tissue health. Hepatica (Hepatica v1) provides trained clinicians with additional information to evaluate the volume and health of a patient's liver on a segmental basis. It is not intended to replace the established procedures for the assessment of a patient's liver health. However, information gathered through existing diagnostic tests, clinical evaluation of the patient, as well Hepatica (Hepatica v1), may support surgical decision making."	"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."
Target Population	Patients who are suitable to undergo an MRI scan and not contra-indicated for MRI. Hepatica may benefit the clinical management of patients who are being considered for liver resection(s).	Patients suitable to undergo an MRI scan and not contra-indicated for MRI

Comparison of Subject and Predicate Device		
Characteristic	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
Device User	Trained Perspectum internal operator	Trained Perspectum internal operator
Report User	An interpreting clinician or healthcare practitioner	An interpreting clinician or healthcare practitioner
Device Use Environment	Installation of Hepatica v1 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 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.
Clinical Setting	Hepatica v1 is a standalone software device that is intended to be installed on general use workstations at Perspectum's image analysis centres. The intended device users will log on to the workstations, access the device, and use the device on general-use HD monitors. Hepatica v1 is a post-processing software and the intended device users are trained Perspectum internal operators. Operators use Hepatica v1 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 Hepatica v1 reports.	LMSv4 is a standalone software device that is intended to be installed on general use workstations at Perspectum's image analysis centres. 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 and the intended device users are trained Perspectum internal 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 report, are clinicians who receive and interpret LMSv4 reports.
Anatomical Location	Abdomen, including the Liver	Abdomen, including the liver
Energy Considerations	Hepatica is a standalone software application. It does not deliver, monitor or depend on energy delivered to or from patients.	LMS is a standalone software application. It does not deliver, monitor or depend on energy delivered to or from patients.
Design: Purpose	Hepatica is a standalone software application that imports MR datasets encompassing the abdomen, including the liver. Visualisation and display of T1-weighted MR data which can be analysed, and quantitative metrics of tissue characteristics and liver volume are then reported. Datasets imported into Hepatica are DICOM 3.0 compliant and 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 3D visualisation of the liver and quantification of metrics (cT1, PDFF and volumetry) from liver tissue and exportation of results and images to a deliverable report.	Allows for the visualisation via parametric maps and quantification of metrics (cT1, T2* and PDFF) from liver tissue and exportation of results and images to a deliverable report.

Comparison of Subject and Predicate Device		
Characteristic	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
	Hepatica v1 allows for: Volumetry • Reporting of whole liver and segmental volume • Semi-automatic segmentation of the outer contour of the liver • Semi-automatic segmentation of the liver into Couinaud segments via placed landmarks of anatomical areas of interest cT1 and PDFF metrics may be quantified and loaded from LMS when analysis has been conducted on the same patient. Datasets imported from LMS contain all image analysis warnings and cautions associated with the individual analysis and are included in the hepatica report.	LMSv4 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 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 (1) 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 (2)
Design: MR Relaxometry	Hepatica v1 does not support quantification of metrics from MR relaxometry. If cT1 results are imported from LMS, cT1 may be reported for all individual Couinaud segments and for whole-liver analysis. Median T2* values are given from the cT1 quantification.	T1, iron- and fat- corrected T1 (cT1) and T2* mapping
Design: Liver Fat Quantification	Liver fat quantification data is imported from the predicate device (LMSv4), where available. If PDFF results are imported from LMS, PDFF may be reported for all individual Couinaud segments as well as Whole-liver PDFF based on the segmented outer-	Utilizes MR images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat using the LMS IDEAL method (2).

Comparison of Subject and Predicate Device		
Characteristic	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
	contour. PDFF parametric maps are calculated using the LMS IDEAL method (2).	
Design: Liver Segmentation	Hepatica v1 supports semi-automatic liver segmentation of T1-weighted volumetric data. Liver segmentation in Hepatica v1 requires the placement of anatomical landmarks to define the outer contours of the liver and can be adjusted by the operator, where necessary. Where available, whole liver and segmental cT1 and PDFF quantitative metrics derived from the predicate device may be presented in the final report.	LMSv4 supports automatic multi-slice full liver segmentation of the cT1 and PDFF parametric maps. 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 liver vasculature excluded from the segmented volume.
Design: Regions of Interest (ROI)	Does not support ROI functionality.	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. Also supports the display of 'Live' ROI statistics when moving the ROI across the parametric map.
Design: Parametric Maps	Hepatica uses volumetric datasets to create 2D anatomical views from all supported scanners. Where available, cT1 and PDFF parametric maps are derived from the predicate device.	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* and PDFF measurements and the scanner field strength to correct for signal changes related to iron deposits, producing a cT1 map. The cT1 map eliminates the effects of elevated iron from the T1 measurement (3) and standardizes for the fat signal across scanner manufacturers. 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.

Comparison of Subject and Predicate Device		
Characteristic	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
Design: Visualisation	Numerous views in the Hepatica v1 interface can be used to assist analysis. Operators are able to see live views of crosshair placements during landmarking across multiple image planes simultaneously and adjust contrast where required. Lesion segmentation will be performed by navigating through the axial slices using the crosshair tool and "painting in" the segment on each slice. Operators will be required to navigate through the axial, sagittal and coronal planes using the crosshair tool to confirm that the delineation carried out by the device is accurate. The borders can be adjusted accordingly. Views of the segmented liver and lesions are updated in real-time and can be rotated in a 3D space. Paint, eraser and zooming functionalities are also available to the operator. Where available, operators can review the position of cT1 and PDFF slices (derived from LMSv4) within the 3D view of the liver.	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.
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 of liver volume and tissue characteristics are collated into a report for evaluation and interpretation by a clinician. <u>Images</u> Images of the whole liver divided into Couinaud segments are presented in greyscale in the report. Where available, cT1 and PDFF slices are also presented from the imported LMSv4 analysis. <u>Values</u> Whole and segmental liver volume metrics calculated during analysis are provided in the report.	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 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.

Comparison of Subject and Predicate Device		
Characteristic	Hepatica v1 (Subject device)	LMSv4 (Predicate device)
	Where available, whole liver segmental cT1 and PDFF values are provided. For each metric, the median, IQR and a 'reference range' are provided.	Based on the placed ROIs, for each metric the median and IQR are given as well as a 'reference range'.
Compatibility with the environment	Installation of Hepatica v1 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 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.
Performance	Device performance was assessed with previously acquired in-vivo data from healthy and non-healthy volunteers.	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.'	Assessed in accordance with IEC 62366 and FDA guidance document 'Applying Human Factors and Usability Engineering to Medical Devices.'
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
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

Hepatica 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 Hepatica v1 is at least as safe and effective as the predicate device and does not introduce any new risks.

5.1. Performance Testing - Clinical

To assess the accuracy and precision of Hepatica v1 measurements across supported scanners, previously acquired 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. The results of which are summarized below:

Accuracy

Metric	Volume (% of total liver volume)	cT1	PDFF
Liver Segment	Upper and Lower Limits of Agreement	Upper and Lower Limits of Agreement	Upper and Lower Limits of Agreement
Segment 1	-0.49% to 0.95%	-1.13% to 0.61%	-0.26% to 0.21%
Segment 2	-3.09% to 5.06%	-2.38% to 1.56%	-0.33% to 0.38%
Segment 3	-5.01% to 3.9%	-1.51% to 1.31%	-0.16% to 0.17%
Segment 4a	-4.60% to 4.26%	-0.77% to 1.10%	-0.30% to 0.23%
Segment 4b	-5.50% to 2.56%	-1.32% to 1.13%	-0.16% to 0.14%
Segment 5	-1.54% to 3.38%	-1.11% to 0.87%	-0.16% to 0.18%
Segment 6	-4.34% to 4.29%	-1.00% to 0.83%	-0.16% to 0.26%
Segment 7	-3.30% to 1.79%	-0.88% to 0.64%	-0.12% to 0.18%
Segment 8	-3.86% to 5.54%	-0.91% to 1.09%	-0.24% to 0.32%
Whole liver	-4.16% to 0.54%	0.00% to 0.00%	-0.02% to 0.02%

Table 2: Performance testing results for Hepatica v1 accuracy when compared to the gold standard (radiologists)

Precision

Liver Segment (% of total liver volume)	Repeatability	Reproducibility
	Upper and Lower limits of Agreement	Upper and Lower Limits of Agreement
Segment 1	-0.72% to 0.65%	-1.39% to 0.90%
Segment 2	-3.06% to 3.24%	-3.10% to 3.15%
Segment 3	-2.67% to 3.13%	-2.41% to 2.06%
Segment 4a	-2.48% to 2.43%	-2.54% to 2.58%
Segment 4b	-1.82% to 1.96%	-1.70% to 1.74%
Segment 5	-4.45% to 4.45%	-4.97% to 5.94%
Segment 6	-3.60% to 4.10%	-3.69% to 5.40%
Segment 7	-3.32% to 3.33%	-4.39% to 3.59%
Segment 8	-4.99% to 3.81%	-6.23% to 5.04%
Whole liver	-6.15% to 3.78%	-16.6% to 6.95%

Table 3: Pooled performance testing results for Hepatica v1 precision

Performance testing of Hepatica v1 demonstrates that:

- Metrics reported by Hepatica v1 (cT1, PDFF and volumetry in the whole liver and in each liver segment) are comparable to the gold standard (considered to be radiologists)
- Hepatica v1 measurements of volumetry are highly repeatable
- Hepatica v1 measurements of volumetry are highly reproducible
- The variation introduced by operator measurements are well within the acceptance criteria
- cT1 and PDFF measurements reported by Hepatica v1 are within the acceptance criteria set for the predicate device.

5.2. Clinical Investigation

No clinical investigations or studies were conducted during performance testing of Hepatica v1.

6. Conclusion

The subject device is substantially equivalent to the predicate device, and is based on the following observations:

- The indications for use and intended use of the subject device fall within the general tool-type claims of the predicate device.
- The subject device and predicate device both support multi-slice MR data acquired using the specific acquisition protocols, from supported MR systems, to acquire the input data.
- The subject and predicate devices include software applications which utilise MR data to visualise and enable quantification of physiological characteristics in the liver to provide measurements which may be used to assess liver health.
- Both the subject device and the predicate device include applications to facilitate the import and visualization of MR data sets and include tools to enable the manipulation of the views and to enable the quantification and analysis of tissue characteristics in the liver from the MR data.
- The subject and predicate device are both standalone software applications to facilitate the import and visualization of MR data sets.
- The subject and predicate devices enable the quantification of analysis of tissue characteristics in the liver from the MR data.
- 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.
- The subject and predicate device reports all include tabular display of quantification statistics, parametric map images and include normal range references.
- Both the subject and predicate devices are designed to run on general-purpose computing hardware.
- Both the subject and predicate device are intended to be used in the same use environment and by trained Perspectum operators.
- Performance testing demonstrates that the subject device performs at least as safely and effectively as the proposed predicate device.

References

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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).