Perspectum
Keri Hildick
Chief Strategy Officer
Gemini One
5220 John Smith Drive
Oxford, Oxfordshire OX4 2LL
United Kingdom

March 13, 2024

Re: K233930
Trade/Device Name: MRCP+ version 2 (MRCP+ v2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 14, 2023
Received: March 1, 2024

Dear Keri Hildick:

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.

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,

Jessica Lamb

Jessica Lamb, Ph.D.
Assistant Director
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DHT8B: Division of Radiological Imaging
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Office of Product Evaluation and Quality
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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)*

K233930

Device Name

MRCP+ version 2 (MRCP+ v2)

Indications for Use *(Describe)*

MRCP+ v2 is indicated for use as a software-based image processing system for noninvasive, quantitative assessment of biliary system structures.

MRCP+ v2 calculates quantitative three-dimensional biliary system models that enable the measurement of bile duct widths and quantification of strictures and dilatations. MRCP+ v2 includes tools for interactive segmentation and labelling of the biliary system, including the gallbladder.

MRCP+ v2 provides metrics for interpretation by trained physicians to assist in the assessment of the biliary system. These metrics support physicians in the visualization, evaluation and reporting of hepatobiliary structures.

MRCP+ v2 is designed to utilize DICOM-compliant MRCP datasets acquired on supported MR scanners using supported MRCP acquisition protocols.

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: 12th March 2023

1 Submitter Details

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2 Subject and Predicate Device

	Subject Device	Predicate Device
510(k) number	K233930	K183133
Legal Manufacturer	Perspectum Ltd.	Perspectum Ltd.
Owner/Owner Operator Number	10056574	10056574
Device Name	MRCP+ version 2 (MRCP+ v2)	MRCP+ (MRCP+ v1)
Proprietary/Common name	MRCP+	MRCP+
Panel	Radiology	Radiology
Regulation	892.2050	892.2050
Risk Class	Class II	Class II
Product Class code	LLZ	LLZ
Classification	System, Image Processing, Radiological	System, Image Processing, Radiological

3 Subject Device Description

3.1 General Description

MRCP+ v2 is a standalone software medical device. The purpose of the MRCP+ v2 device is to assist a trained operator with the quantitative evaluation of biliary system structures acquired from magnetic resonance (MR) images from a single time-point (a patient visit). A Perspectum-trained operator loads previously acquired magnetic resonance cholangiopancreatography (MRCP) data as input into the MRCP+ v2 device. A structured summary report is generated as output by the device, which includes quantitative analysis results and geometric characteristics of the biliary system and pancreatic ducts. The MRCP+ v2 report is intended to facilitate reporting by a radiologist for subsequent interpretation and to aid diagnosis by a physician as part of a panel of testing, including conventional radiological tools.

MRCP+ v2 is designed to utilize Digital Imaging and Communications in Medicine (DICOM)-compliant MRCP datasets acquired on supported MR scanners to display the fluid-filled tubular structures in the abdomen, including intra- and extra-hepatic biliary tree, gallbladder, and pancreatic duct system. Analysis and evaluation tools in MRCP+ v2 include segmentation of structures utilizing user input of seeding points, interactive labelling of segmented areas, and quantitative measurement derived from segmentation results. MRCP+ v2 calculates quantitative three-dimensional biliary system models that enable measurement of bile duct widths and automatic detection of regions of variation in the width of tubular structures, including those quantified as strictures and dilations. MRCP+ v2 includes tools allowing for regional volumetric analysis of segmented tree-like, tubular structures and the gallbladder.

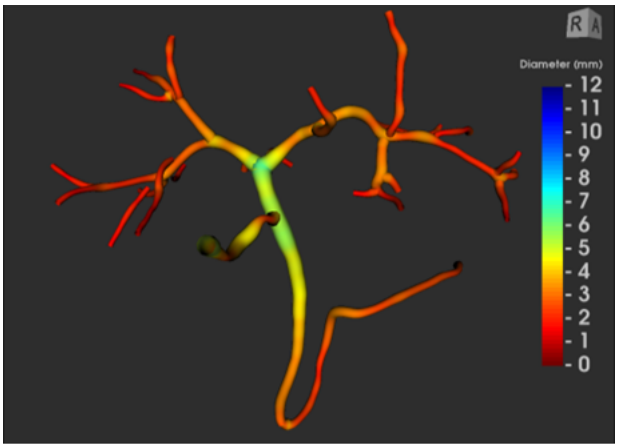

Figure 1: 3D image of the biliary tree constructed from MRCP data using MRCP+ and color coded according to duct widths (mm)

The MRCP+ v2 report is intended to supplement conventional radiology reports. MRCP+ v2 does not replace the usual procedures for assessing the biliary system by a reviewing radiologist or interpreting physician, providing many opportunities for competent human intervention in the interpreting images and information. A radiologist or physician must also consider the device's limitations and accuracy when reviewing or interpreting MRCP+ v2 results and reports. Therefore, MRCP+ v2 presents a low level of concern with respect to patient safety since its metrics only augment the clinical information utilized by radiologists and physicians for the medical management of patients.

3.2 Indications for Use

MRCP+ v2 is indicated for use as a software-based image processing system for noninvasive, quantitative assessment of biliary system structures.

MRCP+ v2 calculates quantitative three-dimensional biliary system models that enable the measurement of bile duct widths and quantification of strictures and dilatations. MRCP+ v2 includes tools for interactive segmentation and labelling of the biliary system, including the gallbladder.

MRCP+ v2 provides metrics for interpretation by trained physicians to assist in the assessment of the biliary system. These metrics support physicians in the visualization, evaluation and reporting of hepatobiliary structures.

MRCP+ v2 is designed to utilize DICOM-compliant MRCP datasets acquired on supported MR scanners using supported MRCP acquisition protocols.

3.3 Intended Patient Population

General population — MRCP+ v2 has no demographic or population restrictions. MRCP+ v2 analyzes hepatobiliary structures from appropriately acquired MR datasets.

MRCP+ v2 is not intended to be used for any specific disease or condition. The information provided by the MRCP+ v2 report may offer valuable additional input to support a diagnostic decision when interpreted by a trained physician.

3.4 Contraindications

MRCP+ v2 is suitable for all patients not contra-indicated for MRI.

MRCP+ v2 has the following contra-indications.

- MRCP+ v2 reports should not be used as the sole basis for forming a diagnosis – to do so would constitute a misuse of the device.
- MRCP+ v2 reports should not be used as a control mechanism for biopsy guidance – to do so would constitute a misuse of the device.
- MRCP+ v2 reports should not be used as a direct control mechanism for the delivery of treatment – to do so would constitute a misuse of the device.
- MRCP+ v2 reports should not be used as the sole basis for evaluating the response to treatment – to do so would constitute a misuse of the device.

3.5 Intended Conditions

MRCP+ v2 is not intended to be used for the diagnosis, treatment or monitoring of any specific diseases or conditions.

MRCP+ v2 does not have any demographic restrictions.

MRCP+ v2 is indicated for use in any patient where MRI is not contraindicated.

MRCP+ v2 does not require the use of contrasting agent.

3.6 Biological properties

N/A — MRCP+ v2 is a post-processing standalone software device. MRCP+ v2 does not have any chemical, physical or biological properties and does not incorporate substances which are considered medicinal products or human blood derivatives. MRCP+ v2 does not contain tissues, cells, or substances of animal origin.

3.7 Materials

N/A — MRCP+ v2 is a post-processing standalone software device. MRCP+ v2 does not consist of any physical materials. Thus toxicity, flammability, phthalates, contamination because of the ingress or egress of substances are not applicable to this device.

3.8 Substances

N/A — MRCP+ v2 is a post-processing standalone software device. Risks posed by substances or particles, including wear debris, degradation products and processing residues, are not applicable to this device.

3.9 Lifetime of the device

N/A — MRCP+ v2 is a post-processing standalone software device. The lifetime of the device is indefinite until support for MRCP+ v2 is withdrawn by the manufacturer. The performance characteristics of MRCP+ v2 do not degrade over time. MRCP+ v2 lifetime is dependent on its continued use in accordance with the minimum technical requirements for the operating system, hardware, and browsers.

3.10 Packaging and transport

N/A — MRCP+ v2 is a post-processing standalone software device. The performance characteristics of MRCP+ v2 will not be adversely affected during transport and storage. MRCP+ v2 is operated using general-purpose computing hardware that meets the minimum technical requirements for its use.

3.11 Sterility

N/A — MRCP+ v2 is a post-processing standalone software device. It is non-contact, noninvasive and non-sterile.

3.12 Radiation and energy supply

N/A — MRCP+ v2 is a post-processing software device. It does not emit any kind of radiation. MRCP+ v2 does not supply patients with a source of energy or any other substances.

3.13 Power supply

N/A — MRCP+ v2 is a post-processing software device. The safety of patients does not depend on internal and/or external power supply. MRCP+ v2 does not supply patients with any form of power supply.

3.14 Mechanical properties

N/A — MRCP+ v2 is a post-processing standalone software device. MRCP+ v2 does not emit noise, generate vibrations, or include mechanically moving parts. Compliance with the **Machinery Directive** (2006/42/EC) is not required.

3.15 Personal protective equipment

N/A — MRCP+ v2 is a post-processing standalone software device. Thus, MRCP+ v2 is not intended to be used as a personal protective equipment. Compliance with the **Personal Protective Equipment Directive (2016/425)** is not required.

3.16 Electronic instructions for use

The instructions for use accompanying MRCP+ v2 comply with the **Electronic Instructions for Use of Medical Devices Regulation (207/2012)**.

4 Subject and Predicate Comparison

Table 1 provides a comparison of characteristics between the subject device (MRCP+ v2) and the predicate device (MRCP+ v1) to demonstrate substantial equivalence. Differences between the devices are highlighted.

4.1 Subject Device and Predicate Comparison

The following characteristics were compared between the subject device and the predicate device to demonstrate substantial equivalence. Differences between the devices are highlighted.

Table 1. Comparison between the predicate and subject devices.

Characteristic	MRCP+ v2 (subject device)	MRCP+ v1 (predicate device)
Indications for Use	MRCP+ v2 is indicated for use as a software-based image processing system for noninvasive, quantitative assessment of biliary system structures. MRCP+ v2 calculates quantitative three-dimensional biliary system models that enable the measurement of bile duct widths and quantification of strictures and dilatations. MRCP+ v2 includes tools for interactive segmentation and labelling of the biliary system including the gallbladder. MRCP+ v2 provides metrics for interpretation by trained physicians to assist in the assessment of the biliary system. These metrics support physicians in the visualization, evaluation and reporting of hepatobiliary structures. MRCP+ v2 is designed to utilize DICOM compliant MRCP datasets, acquired on supported MR scanners using supported MRCP acquisition protocols.	MRCP+ v1 is indicated for use as a software-based image processing system for non-invasive, quantitative assessment of biliary system structures by facilitating the generation, visualisation and review of three-dimensional quantitative biliary system models and anatomical image data. MRCP+ v1 calculates quantitative three-dimensional biliary system models that enable measurement of bile duct widths and automatic detection of regions of variation (ROV) of tubular structures. MRCP+ v1 includes tools for interactive segmentation and labelling of the biliary system and tubular structures. MRCP+v1 allows for regional volumetric analysis of segmented tree-like, tubular structures and the gallbladder. Combining image viewing, processing and reporting tools, the metrics provided is designed to support physicians in the visualization, evaluation and reporting of hepatobiliary structures. These models and the physical parameters derived from the models, when interpreted by a trained physician, yield information that may assist in biliary system assessment. MRCP+ v1 is designed to utilize DICOM compliant MRCP datasets, acquired on supported MR scanners using supported MRCP acquisition protocols. MRCP+ v1 is suitable for all patients not contra-indicated for MRI.
Intended Conditions	MRCP+ v2 is not intended to be used for the diagnosis, treatment or monitoring of any specific diseases or conditions. MRCP+ v2 does not have any demographic restrictions. MRCP+ v2 is indicated for use in any patient where MRI is not contraindicated. MRCP+ v2 does not require the use of contrasting agent.	MRCP+ v1 is not intended to be used for the diagnosis, treatment or monitoring of any specific diseases or conditions.

Contraindications	Same as predicate	MRCP+ v1 is suitable for all patients not contra-indicated for MRI. MRCP+ v1 has the following contra-indications. • MRCP+ v1 reports should not be used as the sole basis for forming a diagnosis – to do so would constitute a misuse of the device. • MRCP+ v1 reports should not be used as a control mechanism for biopsy guidance – to do so would constitute a misuse of the device. • MRCP+ v1 reports should not be used as a direct control mechanism for delivery of treatment – to do so would constitute a misuse of the device. • MRCP+ v1 reports should not be used as the sole basis for evaluating the response to treatment – to do so would constitute a misuse of the device.
Device User	Trained Perspectum Operators specifically trained in radiological anatomy.	Trained operator with a background in radiological anatomy, such as an MR radiographer/ MR technician.
Report User	Same as predicate	Interpreting physician reporting radiologist
Device Use Environment	Same as predicate	Installation of MRCP+ v1 is controlled and installed on general purpose workstations at Perspectum's image analysis centre. In the context of use, MRCP+ v1 reports are made available through QAS.
Clinical Setting	Same as predicate barring the change to device user.	The MRCP+ v1 device is a standalone software device and prior to use shall be installed on general use workstations at the manufacturer's facilities. The intended users (trained radiographers) will log on to the workstations, access the device, and use the device on general use HD monitors. The intended end users of MRCP+ v1 are clinicians or expert radiologists who receive and interpret MRCP+ v1 report through the QAS portal where DICOM data is uploaded and reports are downloaded.
Anatomical Location	Same as predicate	MRCP+v1 uses acquired MR images of the mid-abdominal area in humans. MRCP+ v1 is intended to be used in the assessment of the biliary tree and gallbladder structures and has quantification tools for

		interactive segmentation and labelling of these structures.
Energy Considerations	Same as predicate	Software only application. The device, a standalone software application, does not deliver or depend on energy delivered to or from patients.
Design: Purpose	Same as predicate	Standalone software application to facilitate the import and visualization of MR data sets encompassing the abdomen, including the liver with functionality independent of the MRI equipment vendor. Combining image viewing, processing and reporting tools, the metrics provided is designed to support physicians in the visualization, evaluation and reporting of hepatobiliary structures.
Design: Tools	MRCP+ v2 calculates quantitative three-dimensional biliary system models that enable measurement of bile duct widths and automatic detection of regions of variation (ROV) in width of tubular structures. MRCP+ v2 includes tools for interactive segmentation and identification of the biliary system and tubular structures. MRCP+ v2 allows for regional volumetric analysis of segmented tree-like, tubular structures and the gallbladder. MRCP+ v2 includes tools for the removal of Gastro-Intestinal (GI) contamination from incoming MRCP data. MRCP+ v2 also includes tools for improved operability, allowing operators to select and name a duct from a dropdown list. This replaces the manual step of typing the duct name under analysis.	MRCP+ v1 calculates quantitative three-dimensional biliary system models that enable measurement of bile duct widths and automatic detection of regions of variation (ROV) of tubular structures. MRCP+ v1 includes tools for interactive segmentation and identification of the biliary system and tubular structures. MRCP+ v1 allows for regional volumetric analysis of segmented tree-like, tubular structures and the gallbladder.
Performance Features	Same as predicate	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
Design: Algorithms	Same as predicate	MRCP+ uses algorithms to: • Identify the gallbladder • Identify and enhance tubular structures • Remove shape based small objects • Modelling of the Biliary Tree

		• Adding and removing branches from the Biliary Tree • Estimate tube width and other metrics such as duct length
Design: Gallbladder Segmentation	Same as predicate	MRCP+ v1 supports semi-automatic segmentation of the gallbladder form the Biliary tree. Automatic gallbladder identification is completed by the MRCP+ v1 device and is reviewed and modified by the operator where necessary. Segmentation is completed by the MRCP+ v1 device.
Design: Visualization	Numerous views (2D and 3D) in the MRCP+ v2 interface can be used to assist analysis. These include: • Enhanced MRCP volume • Quantitative biliary tree model with the duct width color map and with the strictures and dilatations color map • maximum Intensity Projection (MIP) of the biliary tree • Unfolded duct width graphic Operators can see live views of crosshair placements during landmarking across multiple image planes simultaneously and adjust contrast where required. Operators will be required to navigate through the axial, sagittal and coronal planes using the crosshair tool to confirm that the 3D visualization of the biliary tree is accurate. Operators will be able to remove Gastro-Intestinal (GI) contamination from incoming MRCP data. Operators will be able to select and name a duct from a dropdown list. This replaces the manual step of typing the duct name under analysis.	Numerous views (2D and 3D) in the MRCP+ v1 interface can be used to assist analysis. These include: • Enhanced MRCP volume • Quantitative biliary tree model with the duct width colour map • maximum Intensity Projection (MIP) of the biliary tree • Unfolded duct width graphic Operators can see live views of crosshair placements during landmarking across multiple image planes simultaneously and adjust contrast where required. Operators will be required to navigate through the axial, sagittal and coronal planes using the crosshair tool to confirm that the 3D visualization of the biliary tree is accurate.
Design: Supported Modalities	Same as predicate	DICOM 3.0 compliant MR data.
Design: Output	Reporting Quantified metrics and images derived from the analysis of the biliary tree are exported from MRCP+ v2 are collated and delivered into a report to be evaluated and interpreted by a licensed physician. Images	Reporting Quantified metrics and images derived from the analysis of the biliary tree are exported from MRCP+ v1 are collated and delivered into a report to be evaluated and interpreted by a licenced physician. Images

	Images of the whole biliary tree are represented in 4 images within the report:
	• Enhanced MRCP volume
	• Quantitative biliary tree model
	  ○ with the duct width color map
	  ○ with the strictures and dilatations color map
	• A maximum Intensity Projection (MIP) of the biliary tree
	
	Specific biliary duct models are also shown in a 3D image and regions of interest are presented as 2D unfolded duct.
		Images of the whole biliary tree are represented in 3 images within the report:
		• Enhanced MRCP volume
		• Quantitative biliary tree model with the duct width colour map
		• A maximum Intensity Projection (MIP) of the biliary tree
		
		Specific biliary duct models are also shown in a 3D image and regions of interest are presented as 2D unfolded duct.

	<u>Values</u> Biliary tree volume metrics and metrics pertaining to the length and width of the biliary tree are calculated during analysis and provided in the report these include the following. For full Biliary tree metrics: • Biliary tree volume • Gallbladder volume • Total number of ducts • Total number of strictures • Total number of dilatations • Total number of ducts with a stricture or dilatation • Percentage of ducts with median width greater than 3mm up to 5mm For individual identified ducts: • Number of strictures • Total length of strictures • Number of dilatations • Total length of dilatations • Median width • Minimum width • Maximum width	<u>Values</u> Biliary tree volume metrics and metrics pertaining to the length and width of the biliary tree are calculated during analysis and provided in the report these the following. For full Biliary tree metrics: • Biliary tree volume • Gallbladder volume • Total number of ducts • Percent of ducts with median width less than 3mm • Percent of ducts with median width greater than 3mm up to 5mm • Percent of ducts with median width greater than 5mm up to 7mm • Percent of ducts with median width greater than 7mm For individual identified ducts: • Median width • Minimum width • Maximum width • Width inter-quartile range
	<u>Regions of interest</u> Reporting of statistics on whole trees, individual named ducts with strictures and dilatations, snapshots of parametric maps, and comments entered by a trained operator related to the built model and the selected duct(s).	<u>Regions of interest</u> Reporting of statistics on whole trees and individual ducts, snapshots of parametric maps, and comments entered by a trained operator related to the initial model and the selected duct(s).
	<u>Outputted file formats:</u> • PDF • JSON	<u>Outputted file formats:</u> • PDF

Compatibility with the environment	Same as predicate	Installation of MRCP+ v1 is controlled and is installed on general purpose workstations at Perspectum's image analysis center. MRCP+ v1 reads in local files compliant with DICOM 3.0.
Performance	Same as predicate	Validated with digital synthetic phantoms/raw data, phantom scans, and in-vivo (healthy volunteer and patients with suspected hepatobiliary disease) scans.
Human Factors	Same as predicate	Assessed in accordance with IEC 62366 and FDA guidance document 'Applying Human Factors and Usability Engineering to Medical Devices.'
Supported MRI Systems	Same as predicate	GE, Philips, Siemens 1.5T and 3T, MRI systems are cleared for use and supported by Perspectum MRCP+ v1 software. Note: On Siemens devices, MRCP+ v1 i1 supported on software versions VB and onwards.
Standards	Same as predicate	IEC 62304, IEC 62366-1, DICOM 3.0, ISO 14971, ISO 13485
System/Operating System	Same as predicate	Apple/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

5 Software Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff: "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices." The software level of concern for MRCP+ v2 is Moderate, as per FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This device does not control a life supporting or life-sustaining device, nor does it control the delivery of a potentially harmful energy. This device does not control the delivery of treatment, and it does not provide diagnostic information, nor does it provide any vital signs monitoring. The hazard analysis identifies the potential software-related risks of using the device, and the mitigations implemented.

6 Performance Testing

MRCP+ v2 underwent performance testing under controlled conditions to corroborate that it is safe and effective when used as intended. The performance testing conducted demonstrates that MRCP+ v2 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

6.1 Performance Testing - Bench

To evaluate the accuracy, repeatability, and reproducibility of the device, phantoms were used to assess the metrics introduced in MRCP+ v2.

The findings from the performance testing affirm that MRCP+ v2 effectively measures strictures and dilatations using acquired phantom data. The demonstration of substantial equivalence between MRCP+ v2 and the predicate device proves that MRCP+ v2's accuracy carries no additional risks compared to MRCP+ v1. In summary MRCP+ v2 successfully met all the predetermined acceptance criteria outlined in the phantom performance testing.

Accuracy

The accuracy of MRCP+ v2 was determined in two ways: the accuracy of the algorithms and the accuracy of MRCP+ v2 measurements. The accuracy of MRCP+ v2 measurements was determined for each type of scanner (vendor and field strength) by comparing the results from scanned 3D printed phantoms with the ground truth specification used to generate the phantom (i.e., the specification file used to create the phantom). The accuracy of the algorithms was assessed in an idealized situation by comparing a digital synthetic phantom (constructed, in silico, from duct configuration files) with the ground truth specification.

Repeatability and Reproducibility

The repeatability and the reproducibility of MRCP+ v2 device was assessed by scanning the 3D-printed phantom on different MRI scanners at 1.5T and 3T field strengths and comparing the analyzed scans with the reference scanner or between two scans. The repeatability of the MRCP+ v2 device was determined by the difference between two acquisitions under the same measurement conditions (on, off, and then on the scanner). The reproducibility of the device was determined by scanning the 3D-printed phantoms under different measurement conditions and comparing the results with the reference scanner, Siemens 3T Prisma.

Substantial Equivalence

Substantial equivalence is defined as the demonstration that the subject device — MRCP+ v2 — is as safe and effective as the predicate device, MRCP+ v1. Previously acquired data from Tube Width and Clinical Biliary phantoms were analyzed in MRCP+ v1 and MRCP+ v2, and the pointwise tube width estimates were compared via Bland-Altman plots.

Table 2: Acceptance criteria for the additional MRCP+ v2 individual duct metrics, assessed using the Stricture and Dilatation phantom. LoA - limits of agreement

Metric	Acceptance criteria	
	Maximum bias	Bland-Altman 95% LoA
Duct length (mm)	± 9.5	± 81.3
Stricture length max (mm)	± 1.1	± 14.6
Stricture length mean (mm)	± 1.1	± 14.3
Stricture length sum (mm)	± 1.8	± 17.8
Dilatation length sum (mm)	± 2.2	± 23.2
Dilatation diameter max (mm)	± 0.7	± 6.0
Stricture absolute severity sum (mm)	± 2.0	± 3.8
Dilatation absolute severity sum (mm)	± 3.3	± 5.5
Dilatation absolute severity max (mm)	± 1.1	± 3.8
Stricture relative severity sum (%)	± 18.6	± 76.7
Dilatation relative severity sum (%)	± 407.5	± 520.6
Dilatation relative severity max (%)	±209.6	± 281.2
Stricture score sum (mm)	±1.95	± 8.6
Dilatation score sum (mm)	± 33.3	± 49.6
Number of strictures	± 1.0	± 3.0
Number of dilatations	±1.0	± 3.0

Table 3: Acceptance criteria for the tube width measurements, which are the same as those that were used for the predicate device MRCP+ v1 (K183133). These are assessed using the Tube Width and Clinical Biliary phantoms LoA - limits of agreement

Test	Acceptance criteria			
	Percentage of points stably matched	Absolute value of mean bias	Largest absolute LoA	Slope of bias
Accuracy of algorithm – synthetic data	> 80%	⩽ 0.4 mm	⩽ 1.4 mm	⩽ 0.1 mm per mm
Accuracy of device – acquired data	> 80%	⩽ 0.5 mm	⩽ 1.5 mm	⩽ 0.1 mm per mm
Repeatability	> 80%	⩽ 0.4 mm	⩽ 1.4 mm	⩽ 0.15 mm per mm
Reproducibility	> 80%	⩽ 0.6 mm	⩽ 1.6 mm	⩽ 0.15 mm per mm
Substantial equivalence between MRCP+ v1 and MRCP+ v2	> 80%	⩽ 0.6 mm	⩽ 1.6 mm	⩽ 0.15 mm per mm

Table 4: Acceptance criteria for in vivo performance of summary whole tree metrics. These criteria are presented in phantoms to contextualize the performance in phantoms LoA - limits of agreement

Metric	Acceptance criteria (Bland-Altmann 95% LoA)
Total number of ducts	± 116.2

Total number of strictures	± 16.5
Total number of dilatations	± 33.8
Total number of ducts with a stricture of dilatations	± 27.4
Total number of ducts with a stricture and dilatation	± 9.6
Number of ducts with a stricture	± 12.4
Number of ducts with a dilatation	± 24.5
Duct length mean (mm)	± 12.3
Duct length sum (mm)	± 2082.7
Stricture length sum (mm)	± 121.4
Dilatation length sum (mm)	± 215.8
Abnormal length sum (mm)	± 326.3
Stricture absolute severity sum (mm)	± 32.0
Dilatation absolute severity sum (mm)	± 78.7
Dilatation absolute severity max (mm)	± 4.5
Stricture relative severity sum (%)	± 708.0
Dilatation relative severity sum (%)	± 2437.6
Dilatation relative severity max (%)	± 165.3
Stricture score sum (mm)	± 51.7
Dilatation score sum (mm)	± 179.2
Dilatation diameter max (mm)	± 6.3

6.2 Performance Testing – Clinical

Precision: Repeatability and Reproducibility

MRCP+ v2's performance testing for precision consisted of assessments of repeatability and reproducibility of the metrics using volunteers scanned under the same measurement conditions (twice, on the same scanner, a short time apart for repeatability) and under different measurement conditions (on more than one scanner, compared to a reference scanner for reproducibility). All tests passed the pre-determined acceptance criteria for repeatability tests across all scanner types. The metrics reported by the internal operators can be considered to have good intra-operator and inter-operator agreement and produce consistent results. In all scanners tested, the metrics reported by the internal operators can be considered to have good agreement and produce consistent results even in the worst-case scenario of different scanners and operators.

Table 5: Acceptance Criteria for Repeatability and Reproducibility of Whole Tree Metrics LoA - limits of agreement

Metrics	Repeatability Acceptance Criteria (Bland Altman 95% LoA)	Reproducibility Acceptance Criteria (Bland Altman 95% LoA)
Total number of ducts	±116.2	±116.2
Total number of strictures	±16.5	±16.5
Total number of dilatations	±33.8	±33.8
Total number of ducts with a stricture or dilatation	±27.4	±27.4
Total number of ducts with a stricture and dilatation	±9.6	±9.6

Number of ducts with a stricture	±12.4	±12.4
Number of ducts with a dilatation	±24.5	±24.5
Duct length mean	±12.3 mm	±12.3 mm
Duct length sum	±2082.7 mm	±2082.7 mm
Stricture length sum	±121.4 mm	±121.4 mm
Dilatation length sum	±215.8 mm	±215.8 mm
Abnormal length sum	±326.3 mm	±326.3 mm
Stricture length mean	±8.9 mm	±8.9 mm
Stricture length max	±19.6 mm	±19.6 mm
Stricture absolute severity sum	±32.0 mm	±32.0 mm
Dilatation absolute severity sum	±78.7 mm	±78.7 mm
Dilatation absolute severity max	±4.5 mm	±4.5 mm
Stricture relative severity sum	±708.0%	±708.0%
Dilatation relative severity sum	±2437.6%	±2437.6%
Dilatation relative severity max	±165.3%	±165.3%
Stricture score sum	±51.7 mm	±51.7 mm
Dilatation score sum	±179.2 mm	±179.2 mm
Percentage of ducts with a stricture or dilatation	±23.2%	±23.2%
Dilatation diameter max	±6.3 mm	±6.3 mm
Biliary tree volume	±20 mL	±20 mL
Gallbladder volume	±30 mL	±30 mL
Percentage of ducts with median width less than 3 mm	±40%	±45%
Percentage of ducts with median width greater than 3 mm up to 5 mm	±40%	±45%
Percentage of ducts with median width greater than 5 mm up to 9 mm	±40%	±45%
Percentage of ducts with median width greater than 9 mm	±40%	±45%

Table 6: Acceptance Criteria for Repeatability and Reproducibility of Single Duct Metrics LoA - limits of agreement

Metrics	Repeatability Acceptance Criteria (Bland Altman 95% LoA)	Reproducibility Acceptance Criteria (Bland Altman 95% LoA)
Total number of strictures	±2.0	±2.0
Total number of dilatations	±2.0	±2.0
Duct length	±71.8 mm	±71.8 mm
Stricture length sum	±16.0 mm	±16.0 mm
Dilatation length sum	±21.0 mm	±21.0 mm
Stricture length mean	±13.2 mm	±13.2 mm
Stricture length max	±13.5 mm	±13.5 mm
Stricture absolute severity sum	±1.8 mm	±1.8 mm
Dilatation absolute severity sum	±2.2 mm	±2.2 mm
Dilatation absolute severity max	±2.7 mm	±2.7 mm
Stricture relative severity sum	±58.1%	±58.1%
Dilatation relative severity sum	±113.1%	±113.1%

Dilatation relative severity max	±71.6%	±71.6%
Stricture score sum	±6.6 mm	±6.6 mm
Dilatation score sum	±16.3 mm	±16.3 mm
Dilatation diameter max	±5.3 mm	±5.3 mm
Median duct width	±3 mm	±3.5 mm
Duct width interquartile range	±3.5 mm	±4.0 mm
Maximum duct width	±4.5 mm	±4.8 mm
Minimum duct width	±3.8 mm	±3.8 mm

Inter and Intra-Operator Assessment

To assess the variability between the metrics obtained by different operators, case-matched comparisons were conducted across all reported metrics. Operators were blinded to all analyses conducted by other operators and origins of datasets. The volunteer data used for the precision experiments was also used to assess inter-operator and intra-operator variability of metrics reported by the MRCP+ v2 device among operators. To assess inter-operator variability, two internal operators separately processed the same cases and the metrics obtained by each operator were compared statistically. To assess intra-operator variability, one internal operator processed the same set of cases twice, with the anonymized cases presented in a randomized order each time, and the metrics from each analysis were compared statistically.

Table 7: Acceptance Criteria for Intra and Inter-Operator Assessment, Whole Tree Metrics LoA - limits of agreement

Metrics	Acceptance Criteria (Bland Altman 95% LoA)
Total number of ducts	±116.2
Total number of strictures	±16.5
Total number of dilatations	±33.8
Total number of ducts with a stricture or dilatation	±27.4
Total number of ducts with a stricture and dilatation	±9.6
Number of ducts with a stricture	±12.4
Number of ducts with a dilatation	±24.5
Duct length mean	±12.3 mm
Duct length sum	±2082.7 mm
Stricture length sum	±121.4 mm
Dilatation length sum	±215.8 mm
Abnormal length sum	±326.3 mm
Stricture length mean	±8.9 mm
Stricture length max	±19.6 mm
Stricture absolute severity sum	±32.0 mm
Dilatation absolute severity sum	±78.7 mm
Dilatation absolute severity max	±4.5 mm
Stricture relative severity sum	±708.0%
Dilatation relative severity sum	±2437.6%
Dilatation relative severity max	±165.3 %
Stricture score sum	±51.7 mm
Dilatation score sum	±179.2 mm

Percentage of ducts with a stricture or dilatation	±23.2%
Dilatation diameter max	±6.3 mm
Biliary tree volume	±20 mL
Gallbladder volume	±30 mL
Percentage of ducts with median width less than 3 mm	±45%
Percentage of ducts with median width greater than 3 mm up to 5 mm	±45%
Percentage of ducts with median width greater than 5 mm up to 9 mm	±45%
Percentage of ducts with median width greater than 9 mm	±45%

Table 8: Acceptance Criteria for Intra and Inter-Operator Assessment, Single Duct Metrics LoA - limits of agreement

Metrics	Acceptance Criteria (Bland Altman 95% LoA)
Total number of strictures	±2.0
Total number of dilatations	±2.0
Duct length	±71.8 mm
Stricture length sum	±16.0 mm
Dilatation length sum	±21.0 mm
Stricture length mean	±13.2 mm
Stricture length max	±13.5 mm
Stricture absolute severity sum	±1.8 mm
Dilatation absolute severity sum	±2.2 mm
Dilatation absolute severity max	±2.7 mm
Stricture relative severity sum	±58.1%
Dilatation relative severity sum	±113.1%
Dilatation relative severity max	±71.6%
Stricture score sum	±6.6 mm
Dilatation score sum	±16.3 mm
Dilatation diameter max	±5.3 mm
Median duct width	±2.0 mm
Duct width interquartile range	±2.0 mm
Maximum duct width	±3.0 mm
Minimum duct width	±2.5 mm

Equivalence Testing

Analysis was conducted to compare output measurements of paired subject comparisons between MRCP+ v2 and the predicate device. The operators were blinded to the previous analysis and origins of datasets.

Table 9: Acceptance Criteria for Equivalence Testing of MRCP+ v2 Metrics to the Predicate Device (MRCP+ v1) LoA - limits of agreement

Metric	Acceptance criteria (LoA)
Median duct width	±3 mm
Duct width interquartile range	±3.5 mm

Maximum duct width	±4.5 mm
Minimum duct width	±3.8 mm
Biliary tree volume	±20 mL
Gallbladder volume	±30 mL
Percentage of ducts with median width less than 3 mm	±40%
Percentage of ducts with median width greater than 3 mm up to 5 mm	±40%
Percentage of ducts with median width greater than 5 mm up to 9 mm	±40%
Percentage of ducts with median width greater than 9 mm	±40%

6.3 Clinical Investigation

No clinical investigations or studies were conducted during performance testing of MRCP+ v2.

7 Conclusion

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

- The subject device and predicate device (K183133) are both software-only devices intended to analyze multi-slice MR data acquired using the specific acquisition protocols, from supported MR systems.
- The labelling for both predicate and subject device are consistent with the intended use, both predicate and subject devices are limited to their uses in MR image analysis and not to be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.
- The subject and predicate devices include software applications which utilize MR data to visualize and enable quantification of hepatobiliary characteristics to provide measurements which may be used to assess biliary health.

In conclusion, MRCP+ v2 is substantially equivalent to the legally marketed predicate device in terms of safety and effectiveness. MRCP+ v2 has been rigorously tested and validated, showing high performance for image processing and analysis.

The data provided in this 510(k) summary, including the results of non-clinical and clinical evaluations, support the claim of substantial equivalence. The software complies with all relevant standards and guidelines, ensuring its reliability and safety for intended users.