



June 22, 2026

Quantified Imaging Limited
Armen Bodossian
Chief Technology Officer
23 Alphabet Mews
Unit Z
London, SW9 0FN
United Kingdom

Re: K253421

Trade/Device Name: Perfusion Measurement Platform v1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 4, 2026
Received: June 4, 2026

Dear Armen Bodossian:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253421

?

Please provide the device trade name(s).

?

Perfusion Measurement Platform v1

Please provide your Indications for Use below.

?

The Perfusion Measurement Platform (PMP) v1 is an image processing software device to be used by trained professionals including but not limited to physicians and medical technicians.

The software is hosted on a cloud platform and can be used to perform medical image processing. Data and images are acquired through connection to DICOM compliant imaging devices and modalities. PMP v1 provides automatic semi-quantitative quantification of Arterial Spin Labelling (ASL) data acquired from Magnetic Resonance Imaging (MRI) scanners at 1.5T and 3.0T.

PMP v1 is able to process single-delay and multi-delay ASL data from SIEMENS XA31+, GE 3D ASL scanners to generate multiple perfusion parameters (Relative Cerebral Blood Flow/relCBF, Arterial Transit Time/ATT) and exports the results of ASL image analysis as DICOM images.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

K253421

Perfusion Measurement Platform v1

510(k) Summary

Prepared on: 2026-06-17

Contact Details

Applicant Name	Quantified Imaging Limited
Applicant Address	Unit Z, 23 Alphabet Mews, London, SW90FN United Kingdom
Applicant Contact Telephone	+447521517941
Applicant Contact	Mr. Armen Bodossian
Applicant Contact Email	armen.bodossian@quantified-imaging.com

Device Name

Device Trade Name	Perfusion Measurement Platform v1
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211059	Cereflow V1.2	LLZ

Device Description Summary

The Perfusion Measurement Platform (PMP) v1 is a medical image analysis, processing and storage system, implemented using Python, and is compliant with the DICOM standard. The platform is hosted on Google Cloud Platform. PMP v1 is intended for automatic semi-quantitative quantification of arterial spin labelling (ASL) data acquired from MRI scanners (SIEMENS XA31+, GE 3D ASL) at 1.5T and 3.0T.

PMP v1 can process single-delay and multi-delay ASL data to generate multiple perfusion parameters (Relative Cerebral Blood Flow/ rCBF, Arterial Transit Time/ATT) and exports the results of ASL image analysis as DICOM images. DICOM is a standard format for storing and transmitting medical image data in vendor neutral format and is managed by the DICOM Standards Committee.

The device consists of six modules, namely the orchestrator, the DICOM store module, the event trigger, the pipeline and the poller/pusher modules. The orchestrator is responsible for establishing secure connections to remote customer DICOM servers, providing the secure gateway for transferring DICOM imaging/communication data to and from the platform. The DICOM store module is responsible for temporary storage of input and processed imaging data. The event trigger module is responsible for managing workflows within the platform. The poller module is responsible for polling new images, whereas the pusher is responsible for sending results to customer DICOM server-side.

The pipeline module is responsible for processing raw DICOM images and producing ATT/CBF maps and a quality control report.

Pre- and post-processing includes:

- sorting and checking files to ensure designated protocols are used, having a complete set of reference (M0) image and label/control images
- performing motion correction if provided with label/control ASL data to improve signal-to-noise (SNR)
- use of M0 for scaling / bias correction

PMP performs semi-quantification of perfusion parameters by fitting a fast variational Bayesian kinetic model to account for the relationship between signal intensity and delivery of labeled blood water via perfusion (relCBF single-delay, relCBF/ATT multi-delay)

If provided with a T1-weighted structural image:

- Image Registration of output maps to anatomical image to enable anatomical overlay
- The software applies a range of quality control checks to ensure the quality of acquired ASL data and processed results. These quality control parameters are exported as a report.

The entire workflow is processed on cloud servers, and there is no user interface for this application. PMP v1 is intended to interface with DICOM compliant imaging devices over secure network.

Intended Use/Indications for Use

The Perfusion Measurement Platform (PMP) v1 is an image processing software device to be used by trained professionals including but not limited to physicians and medical technicians.

The software is hosted on a cloud platform and can be used to perform medical image processing. Data and images are acquired through connection to DICOM compliant imaging devices and modalities.

PMP v1 provides automatic semi-quantitative quantification of Arterial Spin Labelling (ASL) data acquired from Magnetic Resonance Imaging (MRI) scanners at 1.5T and 3.0T.

PMP v1 is able to process single-delay and multi-delay ASL data from SIEMENS XA31+, GE 3D ASL scanners to generate multiple perfusion parameters (Relative Cerebral Blood Flow/relCBF, Arterial Transit Time/ATT) and exports the results of ASL image analysis as DICOM images.

Indications for Use Comparison

The predicate device runs on a local workstation whereas PMP v1 runs on a cloud solution. The intended use, however, is the same, with both device used for the analysis of ASL MRI images, producing similar outputs, namely Cerebral Blood Flow maps and Arterial Transit Time maps.

Technological Comparison

Software Languages

The software languages used by the two devices differ.

Deployment Environment

PMP v1: runs on the cloud, the predicate runs on a local workstation.

Inputs

PMP v1: inputs to the device are a subset of the images used as input to the predicate device (less scanner options accepted).

Source of images

PMP v1: Input via connectivity to DICOM server. Different integration approach to import images

Output

Both devices generate multiple perfusion parameters (Relative Cerebral Blood Flow/relCBF, Arterial Transit Time/ATT). Results of ASL image analysis as DICOM images and a report.

Model

PMP v1: Semi-quantification of perfusion parameters by fitting a fast variational Bayesian kinetic model to output relCBF/ATT maps. The devices use a different model to fit the ASL data.

Quality Control

Both devices apply a range of quality control checks to ensure the quality of acquired ASL data and processed results. These quality control parameters can also be exported as a report.

Viewing Images

PMP v1: has no viewer incorporated.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-clinical performance testing was conducted to evaluate whether the technological differences between the subject device, Perfusion Measurement Platform (PMP) v1, and the predicate device, CereFlow™ V1.2 (K211059), affect safety or effectiveness relevant to substantial equivalence.

The Subject device has the same intended use and similar technological characteristics as the Predicate device. The submitted performance data support that any technological differences do not raise different questions of safety and effectiveness under specified use conditions.

Non-clinical testing focused on areas in which the differing technological characteristics of the Subject device and Predicate device could affect device performance relevant to substantial equivalence. The following differences were addressed through non-clinical performance testing:

- Technological Difference 1: The subject device uses a different model to estimate perfusion parameters from the ASL data.
- Technological Difference 2: The Subject device and the Predicate device use different methods for certain pre-processing and post-processing steps applied to ASL MRI data (for example, motion correction and macrovascular correction).

Because direct testing of the predicate device was not available, non-clinical performance testing was designed to assess the technological differences using representative legally marketed reference device datasets and computational simulation methods.

The Predicate relied, in part, on comparison to the legally marketable GE 3D ASL (K092925) for single-delay relCBF output assessment. Non-clinical performance testing of the Subject device incorporated the same GE reference approach to support comparability for single-delay ASL output. In addition, Siemens reference devices (K213693, K231560) that support multi-delay ASL were included to evaluate multi-delay ASL outputs for relCBF/ATT, which is also supported by the Predicate device.

Reference device data comparison testing was conducted using GE and Siemens datasets to assess agreement and bias of PMP output parameters relative to representative legally marketed reference methods. Two reference device datasets with varying physiological / demographic / acquisition factors were available from each of the GE and Siemens devices for comparing performance and addressing bias in relCBF and ATT outputs.

Computational simulation tests were conducted to compare accuracy of model fits between PMP and reference devices, in order to evaluate PMP performance across a wide range of physiological ground truth values / typical acquisition artifacts.

Additional verification and validation activities included:

- Software verification and validation testing was conducted to confirm that the software functions perform as intended.
- Cybersecurity testing was conducted to support the device's secure operation in the intended use environment.

- Human factors / usability validation testing was conducted to evaluate user understanding of device functions and interpretation of device outputs.

The following FDA guidance documents were referenced in development of the non-clinical testing strategy and supporting documentation:

- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, December 2019
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions, April 2022
- Assessing the Credibility of Computational Modelling and Simulation in Medical Device Submissions, November 2023
- Applying Human Factors and Usability Engineering to Medical Devices, February 2016
- FDA draft guidance "Content of Human Factors Information in Medical Device Submissions", Dec 2022
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, FDA, February 2026

FDA-Recognized Consensus standards followed as part of non-clinical testing strategy:

ISO 14971:2019

IEC 62304:2006+A1:2015

IEC 62366-1:2015

NEMA PS3.1-3.20 2024e

Computational simulation testing demonstrated that PMP and reference devices achieved statistically similar performance in estimating ground truth perfusion across a range of physiological values, including in the presence of image acquisition artifacts that are common to ASL.

Comparison of PMP output parameters with Siemens and GE reference device data demonstrated comparable performance characteristics and acceptably low levels of bias, supporting the conclusion that the technological differences do not adversely affect performance relevant to substantial equivalence

Substantial Equivalence Conclusion:

PMP v1 has the same intended use as the predicate device and similar technological characteristics, with identified differences in perfusion estimation modelling and pre-/post-processing of ASL MRI data. The submitted non-clinical performance data, together with software verification and validation, human factors/usability validation, and cybersecurity testing, support that these differences do not raise different questions of safety and effectiveness. Therefore, PMP v1 is substantially equivalent to the predicate device.