Medimagemetric LLC
℅ Yi Wang
President & CEO
455 Main Street, #7H
NEW YORK NY 10044

July 22, 2021

Re: K210415
Trade/Device Name: QSM software, QSMetric™
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: June 21, 2021
Received: June 21, 2021

Dear Yi Wang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210415

Device Name

QSM software

Indications for Use *(Describe)*

QSM software (QSMetric™) is intended for use in the post-acquisition image enhancement of 3D MR images of the brain acquired using a gradient-echo sequence at 1.5T, 3T and 7T field strengths. QSM uses phase information to enhance contrast between tissues presenting magnetic susceptibility differences, such as deoxygenated blood, iron or calcium deposits. When used in combination with other clinical information, QSM may aid the qualified physicians in visualizing tissue structures with magnetic susceptibility contrasts and measuring their susceptibility values.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K210415

510(k) Summary (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

General information

Submitter: Medimagemetric LLC
171 Floral Ave
Johnson City, New York 13790
Contact Yi Wang
Tel: 929.314.2988
Prepared on: 2/8/2021

Device name and classification

Trade name: QSMetric™
Common name: Radiological image processing software
Classification: Magnetic resonance diagnostic device (21 CFR 892.1000, Product code LNH)

Legally marketed device of substantial equivalence (SE) – predicate device

SWIp from PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. (595 MINER RD, Cleveland, OH 44143), cleared for US commercialization via K131241 on 8/30/2013.

Device description

The product QSMetric™, also referred to as QSM software, postprocesses gradient echo magnetic resonance (MR) images to depict tissue magnetic susceptibility contrast (local difference). Tissue susceptibility contrast sources include highly paramagnetic iron presented in deoxyhemoglobin, ferritin and hemosiderin, and diamagnetic calcification. Susceptibility contrast material of tissue in the MR scanner generates its own magnetic field according to the convolution law in magnetism. This tissue field with its dispersion in space causes MR image signal magnitude loss, creating contrasts in magnitude images. Therefore, the magnitude image is commonly used to indicate the presence of nearby tissue susceptibility contrast.

In addition to magnitude images, a gradient echo MR scan results in also phase images. The tissue field causes MR image signal phase accrual, creating contrasts in phase images. The phase image of gradient echo MR data is the product of echo time and tissue field. Accordingly, the phase images from a gradient echo MR scan is processed using QSM to enhance the depiction of tissue susceptibility contrasts.

QSM software works in conjunction with any FDA cleared third-party DICOM viewer as an image postprocessing solution in radiological service.

Intended use

QSM software (QSMetric™) is intended for use in the post-acquisition image enhancement of 3D MR images of the brain acquired using a gradient-echo sequence at 1.5T, 3T and 7T field strengths. QSM uses phase information to enhance contrast between tissues presenting magnetic

susceptibility differences, such as deoxygenated blood, iron or calcium deposits. When used in combination with other clinical information, QSM may aid the qualified physicians in visualizing tissue structures with magnetic susceptibility contrasts and measuring their susceptibility values.

Technological characteristics: substantial equivalence between QSM and predicate SWIp

QSM's fundamental technological characteristics are substantially equivalent to those of the predicate device SWIp (K131241) as described in this submission. The substantial equivalence between QSM and SWIp are noted in the following table.

Features specifications	Subject device QSM software	Predicate device SWIp, K131241	QSM-SWIp SE
Regulation name	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device	Yes
Prescription use	Yes	Yes	Yes
Intended use	QSM software (QSMetric™) is intended for use in the post-acquisition image enhancement of 3D MR images of the brain acquired using a gradient-echo sequence at 1.5T, 3T and 7T field strengths. QSM uses phase information to enhance contrast between tissues presenting magnetic susceptibility differences, such as deoxygenated blood, iron or calcium deposits. When used in combination with other clinical information, QSM may aid the qualified physicians in visualizing tissue structures with magnetic susceptibility contrasts and measuring their susceptibility values.	SWIp is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems. It's indicated for magnetic resonance imaging of the brain. SWIp is a technique using phase information to enhance contrast between tissues presenting susceptibility differences, such as deoxygenated blood or some mineral deposits (e.g. calcium deposits). Due to this contrast enhancement, SWIp images are sensitive for structures containing venous blood such as cerebral venous vasculature. When used in combination with other clinical information, SWIp may help the expert radiologist in the diagnosis of various neurological pathologies.	Yes
MRI system	MRI systems from General Electric, Philips, Siemens, and United Imaging	3.0T and 1.5T, Achieva and Ingenia MRI systems from Philips	Yes
Input data	3D gradient echo magnitude and phase images, or real and imaginary images	gradient echo magnitude and phase images	Yes
Phase processing	Phase unwrapping Background field removal	Phase unwrapping Background field removal	Yes

	Dipole phase modeling to measure susceptibility contrasts with phase and magnitude info	Spectral phase modeling to enhance susceptibility contrasts with phase and magnitude info	
User interface	Automated postprocessing	Automated postprocessing	Yes
Output	Tissue susceptibility contrast map	Images with enhanced contrasts between tissues with susceptibility differences	Yes

SE-Nonclinical performance data

The following design control, risk management and quality assurance methodologies were utilized to develop QSM software:

- Quality policy and system establishment
- Software requirements specification review
- Software design review
- Risk management
- Traceability analysis
- Verification testing at unit and integration levels
- Validation testing on simulated use and nonclinical use.

Software documentation for Moderate Level of Concern software per the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, is also included in this premarket notification submission. The QSM software has been tested in accordance with Medimagemetric's verification and validation procedures.

All predefined acceptance criteria for the engineering performance testing were met for all test cases across different scanner manufacturers. The results from the nonclinical testing performed on the QSM software demonstrate that the QSM software produces results consistently according to its intended use and is substantially equivalent to combining information from SWIp both magnitude and phase images output from the predicate device.

SE-Clinical performance data

The subject device of this premarket notification, QSM software, did not require clinical studies to support substantial equivalence to the predicate device. All predefined acceptance criteria for clinical validation testing, including clinical user needs testing, as a part of the QSM performance validation testing efforts, were met across all test cases. The results of the clinical validation related testing performed on the QSM software demonstrate that output image quality are acceptable, all clinical user needs are met, and QSM is substantially equivalent to combining information from SWIp both magnitude and phase images output from the predicate device.

Conclusions from nonclinical and clinical performance data

The subject device and the predicate device are substantially equivalent, with respect to intended use, instructions for use, design features, technological characteristics, manufacturing methods,

performance criteria, safety, and effectiveness. The subject device is substantially equivalent to the predicate device (K131241) noted herein.