



Medic Vision - Imaging Solutions Ltd
% Mr. Dan Laor
Q&R Advisor
6 Sireni St.
Haifa, 3297206
ISRAEL

March 8, 2018

Re: K173605

Trade/Device Name: iQMR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 19, 2018
Received: February 27, 2018

Dear Mr. Laor:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173605

Device Name

iQMR

Indications for Use (Describe)

The iQMR is intended for networking, communication, processing and enhancement of MRI images in DICOM format. The device processing is not effective for lesion, mass, or abnormalities of sizes less than 1.5mm. This device is indicated for use by qualified trained medical professionals.

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.

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510(k) Summary of Safety and Effectiveness

Submitter details

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Submission Contact: Dan Laor
Israel.

6 Sireni St., Haifa, 3297206,

Details of the submitted Device

Proprietary Name:	iQMR
Regulation Number	892.2050
Product Code:	LLZ
Committee/Panel:	Radiology
Device Class:	2

Type of 510(k) Submission:

Traditional

Identification of the Legally Marketed Predicate Device

K993802 *SharpView*

Device Description

iQMR is a software package that is aimed to process MRI images. The iQMR processing enhances MRI images by reduction of the image noise. The software runs on a PC server, which is connected to the Local Area Network (LAN). The device receives MRI images from different work stations over the network in DICOM format, processes the images and transmits them in DICOM format, to selected work stations.

Intended use and indications for Use

The iQMR is intended for networking, communication, processing and enhancement of MRI images in DICOM format. The device processing is not effective for lesion, mass, or abnormalities of sizes less than 1.5mm. This device is indicated for use by qualified trained medical professionals.

Technological Characteristics

The iQMR software package is installed in an off-the-shelf PC server, which include off-the -shelf graphical boards. The Operating System is Linux Ubuntu. The iQMR software package consists of three software modules: The User Interface, Algorithm, and Interface module. Data inputs and output are MRI images in DICOM format.

Performance Tests

Non-Clinical tests

The device software has been verified by testing the software following predefined software test plan.

The iQMR system has been verified by testing that it meets its specified performance, using MRI standard phantoms.

The iQMR performance has been validated by testing it performing its intended and indications for use, in end-user environment.

The above testing methods adhered to state-of-art standards and procedures. The tests results demonstrate that the device output meet the design input and the intended use.

Clinical tests:

Clinical tests were not conducted. However, MRI clinical images were processed in order to ensure that the iQMR conforms to defined user needs and intended uses under actual conditions.

Risk Management

The device risks were managed and controlled following the requirements of ISO 14971 standard. The device hazards were identified, their risk levels were evaluated and mitigation measures were taken to reduce the risk levels. In Medic Vision opinion the benefits of providing the iQMR features, overweight the device residual risks.

Substantial Equivalence

Comparison with the predicate device

Parameter	Predicate Device SharpView (K993802)	Subject Device iQMR
Intended use	<i>Intended for use by qualified trained medical professionals for enhancement of MRI images that are transferred in the network in DICOM format.</i>	The same
21CFR section	892.2050	The same
Product Code	LLZ	The same
<i>Technological Characteristics</i>		
Device nature	SW package	The same
Operating System	Windows	Linux
Data input	MRI images in DICOM format	The same
Data output	MRI images in DICOM format	The same
Processing Algorithms	GOP Enhancement Software	Medic Vision's Algorithms
User Interface	Included	The same

Substantial Equivalence conclusion

The iQMR has the same intended use as the legally marketed SharpView predicate device. The two devices have similar technological characteristics. Results of tests, which were adhered to state-of-art standards and procedures, demonstrate that differences in the technological characteristics do not raise new questions of safety or effectiveness. Based on this discussion, it is Medic Vision’s opinion that iQMR is substantially equivalent in terms of safety and effectiveness to the SharpView (K993802) predicate device.