SEP 7 2012

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 19th, 2012
Submitter:	GE Medical Systems SCS 283, Rue de la Minière 78530 Buc. France
Primary Contact Person:	Helen Peng, RAC Regulatory Affairs Leader GE Healthcare 3000 North Grandview Blvd, W1140 Waukesha, WI 53188, USA Tel: 262-548-5091 Fax: 262-364-2506 Email: hong.peng@ge.com
Secondary Contact Person:	Stephen Slavens , RAC Regulatory Affairs Director GE Healthcare 3000 North Grandview Blvd, W1140 Waukesha, WI 53188, USA Tel: 262-548-4992 Fax: 262-364-2506 Email: Stephen.slavens@ge.com
Device: Trade Name:	MR VesselIQ Xpress
Common/Usual Name:	Advanced Vessel Analysis MR (AVA MR)
Classification Names:	Class II per 21 CFR 892.2050
Product Code:	Picture, Archiving and Communication System LLZ
Predicate Device(s):	K040746 MRA-CMS by Medis Medical Imaging Systems K041521 Volume Viewer Plus by GE Medical Systems
Device Description:	MR VesselIQ Xpress is a post processing analysis software application designed to assist Radiologists, Cardiologists, and other clinicians in the evaluation and assessment of vascular anatomy. MR VesselIQ Xpress is a software package for the Advantage Workstation (AW) platform and AW Server platform. The MR VesselIQ Xpress is an additional tool for the 2D and 3D analysis

of DICOM compliant MR angiographic images/data , providing a number of display, measurements and batch filming/archive features to study user-selected vessels which include but are not limited to stenosis analysis and directional vessel tortuosity visualization.

Intended Use: MR VesselIQ Xpress is intended to provide an optimized non-invasive application to facilitate vascular anatomy and pathology analysis and vascular disease assessment from a set of DICOM 3.0 compliant Magnetic Resonance Angiographic (MRA) images.

Indication for Use MR VesselIQ Xpress is intended to provide an optimized non-invasive application to facilitate vascular anatomy and pathology analysis from a set of DICOM 3.0 compliant 3D contrast-enhanced Magnetic Resonance Angiographic (MRA) images.

MR VesselIQ Xpress is a post processing application which can be used in the analysis of MRA data for the purpose of vascular disease assessment.

This software is designed to assist radiologists and other clinicians in the evaluation and assessment of vascular anatomy and disease with the capability to provide a set of tools for visualizing directional vessel tortuosity, for sizing the vessel and for measuring areas of abnormalities within a vessel.

Technology: The MR VesselIQ Xpress employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MR VesselIQ Xpress and its components comply with the following voluntary standards :

NEMA PS 3.1 - 3.18(2008) Digital Imaging and Communications in Medicine (DICOM) Set.

MR VesselIQ Xpress was designed in compliance with the following Process Standards:

- ISO 13485 - Quality Systems-Model for Quality assurance in design, development, production, installation and servicing of medical device
- ISO 14971 - Medical devices-Application of Risk management to medical devices
- IEC 62304 - Medical device software – Software life cycle processes
- IEC 62366. -Medical devices – Application of usability engineering to medical devices
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The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Unit level testing (Module Verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, MR VesselIQ Xpress did not require clinical studies to support substantial equivalence.

Conclusion: MR VesselIQ Xpress does not result in any new potential safety risks and performs as well as the predicate devices currently on the market. GE Medical Systems SCS considers the MR VesselIQ Xpress to be as safe, as effective as, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems SCS
% Ms. Helen Peng
Regulatory Affairs Leader
GE Medical Systems, LLC dba GE Healthcare
3000 N. Grandview, W1140
WAUKESHA WI 53188

SEP 7 2012

Re: K122164
Trade/Device Name: MR VesselIQ Xpress
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and LNH
Dated: July 19, 2012
Received: July 20, 2012

Dear Ms. Peng:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number : K122164

Device Name: MR VesselIQ Xpress

Indications for Use:

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MR VesselIQ Xpress is a post processing application which can be used in the analysis of MRA data for the purpose of vascular disease assessment.

This software is designed to assist radiologists and other clinicians in the evaluation and assessment of vascular anatomy and disease with the capability to provide a set of tools for visualizing directional vessel tortuosity, for sizing the vessel and for measuring areas of abnormalities within a vessel.

Prescription Use_X___ AND/OR Over-The-Counter Use__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122164