MAY 2 4 2011

510(k) Summary

Date Prepared

May 13, 2011

Submitter

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General Information

Proprietary Name: AZE VirtualPlace – MR Flow Analysis software
Common Name: MR Flow Analysis
Classification Name: System, Image Processing, Radiology
CFR Reference: 21 CFR 892.2050
Class: II
Product Code: 90 LLZ

Predicate Devices

MRI-FLOW analytical software package (K994282) from MEDIS medical imaging systems B.V. and cmr^{42} Cardiac MR Software (K082628) from Circle Cardiovascular Imaging, Inc.

Device Description

AZE VirtualPlace - MR Flow Analysis software is an optional post-processing software designed to be installed on and used with AZE VirtualPlace workstation (cleared under K060453), which accepts, transfers, displays, stores, and digitally process DICOM medical images from a variety of diagnostic imaging systems (such as CT, MRI, or from image archives) for viewing, image

manipulation, communication, printing and quantification. The MR Flow Analysis retrieves velocity-encoded MRI imaging data via electric media (offline), such as CD-ROM, or digital network (online), and facilitates the visualization and quantitative analysis for arterial vessels and heart valves. The MR Flow Analysis enables to calculate blood flow velocity and flow volume in region(s) of interest (ROI[s]) from the velocity-encoded MR data, and provide quantitative and visual analysis by displaying graphical parameters such as Mean/Minimum/Maximum velocity, Standard deviation, Velocity and volume flow as function of time, Stroke volume, and Cardiac output.

Intended Use

AZE VirtualPlace - MR Flow Analysis software for use with AZE VirtualPlace workstation is intended for post-processing of DICOM compliant velocity-encoded MRI imaging data for visualization and quantitative analysis of arterial vessels and heart valves. The MR Flow Analysis enables to calculate and display the parameters: mean/minimum/maximum and standard deviation of blood velocity in region of interest (ROI), velocity and volume flow as function of time, stroke volume and cardiac output, with graphs of the velocity and volume. These parameters may be useful for a trained physician in supporting the determination of a diagnosis.

Technological Characteristics

AZE VirtualPlace - MR Flow Analysis software has similar technological characteristics to the currently marketed predicate devices listed above.

Performance Data (non-clinical or clinical)

AZE VirtualPlace - MR Flow Analysis software is substantially equivalent to the predicate devices based on descriptive data, software features and indications for use. In addition, the AZE VirtualPlace – MR Flow Analysis software was quantitatively validated by comparing its output to that of one of the predicate devices (cmr^{42} Cardiac MR Software) for the same set of test images.

Conclusions

The technological characteristics and performance data for AZE VirtualPlace - MR Flow Analysis software demonstrates it is substantially equivalent to the predicate device.

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

AZE, Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 2 4 2011

Re: K102534
Trade/Device Name: AZE VitualPlace™ – MR Flow Analysis software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 17, 2011
Received: May 18, 2011

Dear Mr. Job:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.0 Indication for Use statement

510(k) Number (if known): Not assigned

Device Name: AZE VirtualPlace™ – MR Flow Analysis software

Indications For Use: AZE VirtualPlace – MR Flow Analysis software option for use with AZE VirtualPlace workstation is intended for post-processing of DICOM compliant velocity-encoded MRI imaging data for visualization and quantitative analysis of arterial vessels and heart valves. The MR Flow Analysis software calculates and displays the following parameters: mean/minimum/maximum and standard deviation of blood velocity in the selected region of interest (ROI); velocity and volume flow as function of time; stroke volume and cardiac output, and provides graphs of the velocity and volume. These parameters may be useful for a trained physician in supporting the determination of a diagnosis.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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