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Section 5 – 510(k) Summary

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

Submitter: GE Hangwei Medical Systems Co.,Ltd.
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Date Prepared: November 03, 2010

Device Name:

Proprietary Name: Brivo MR355/Optima MR360
Classification Name: Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Predicate Devices:

GE 1.5T Signa® HDe Magnetic Resonance System (K052978)
GE Discovery® MR450 System (K083147)

Device Description:

The Brivo MR355 / Optima MR360 is a new MR system that is similar in design to previous GE Healthcare 1.5T MR systems. All utilize superconducting magnets, gradients, and radio frequency coils and electronics to acquire data in single voxel, two dimensional, or three dimensional datasets.

The 1.5T Brivo MR355 / Optima MR360 features a superconducting magnet operating at 1.5 Tesla. The data acquisition system accommodates up to 8 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The 1.5T Brivo MR355 / Optima MR360 is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Indications for Use:

The Brivo MR355/ Optima MR360 is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Brivo MR355/ Optima MR360 reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis

Comparison with Predicate Devices:

The indications for use for the Brivo MR355/Optima MR360 are similar to those for the GE Signa® HDe Magnetic Resonance System and the GE Discovery® MR450.

Comparison statement between BrivoMR355/Optima MR360 and 1.5T Signa® HDe system :

The GE Brivo355/Optima 360 is a new device design that is similar to the previously cleared 1.5T HDe MR system (K052978). The magnet, gradient coil, RF transmit coil and RF amplifier are common with Signa® HDe. The main differences are an increase in the amplitude and slew rate of the gradient output, a fixed patient table option, and a multi-anatomy receiving coil. Both a detachable table and a new fixed patient table are offered with the system in order to meet emerging market customer expectations. A new multi-anatomy receiving coil is included with the GE Brivo MR355/Optima MR360 to provide customers with more coil selections, and to minimize the need to reposition patients during scanning. Changes to the system software include a modified user interface and differences in the software applications offered.

The new multi-anatomy receiving coil is called Express Coil suite, which includes the neurovascular array coil, CTL/spine array coil and body array coil. The system operates on the same principles with workflow improvement by reducing the need to change coils.
The coils can be used individually or combined to provide the anatomical coverage desired. These individual coils of the Express coil suite are equivalent to the neurovascular array coil, CTL/spine array coil and body array coil from the predicate device - Signa HDe:K052978

Comparison statement between BrivoMR355/Optima MR360 and GE Discovery® MR450:

The GE Brivo MR355/Optima MR360 is also similar to the previously cleared Discovery® MR450 1.5T system (K083147). The software and RF receive chain are common with the Discovery® MR450. There are some changes to the user interface to simplify customer operation, but the operation of the system is significantly equivalent to that of the Discovery ® MR450.

The GE Brivo MR355/Optima MR360 system's Simple user interface (Hide Scan Parameters) is

designed for inexperienced customers or others who may have difficulty using the more complex user interface of many MR systems. With fewer parameter selections in theSimple UI, it is easier to understand and learn, less error prone, and less intimidating for inexperienced users. Features of the Simple UI include robost site protocols for routine scans, AutoTR, and slider bar functionality.

With the Favorite Protocol feature, users can easily select their favorite protocols graphically instead of opening the protocol selector window. There are two kinds of favorite protocols:

Ready Favorite Protocols, also called Ready Shortcuts
Custom Favorite Protocols, also called Custom Shortcuts

Ready Favorite Protocols are predefined and cannot be changed by users. Users can designate any of the scan protocols on the system as Custom Favorite Protocols. These protocols may be their mostly used protocols.

AutoTR aims to automatically adjust repetition time (TR) to optimize scan time when prescribing slicesor changing other parametersand at the same time keeping the image contrast with a TR range provided.

The Slider Bar is used to quickly and easily select different scan parameters.

Summary of Studies:

As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured and documented through testing to NEMA, IEC or ISO standards (as referenced throughout this submission and listed in Section 9):

Performance:

Signal-to-noise ratio (SNR)
Geometric distortion
Image uniformity
Slice thickness
Spatial resolution

Safety

Static field strength
Acoustic noise
Gradient output (dB/dt)
RF output (SAR)
Biocompatibility

Clinical

Clinical images collected by volunteer scanning
All images show that the system meets the indications for use.

The 1.5T Brivo MR355/Optima MR360 has been designed to comply with applicable IEC standards. All testing has been executed and passed by a Nationally Recognized Testing Laboratory.

Conclusion:

It is the opinion of GE that the GE Brivo MR355/Optima MR360 is substantially equivalent to the 1.5T Signa® HDe MR System and GE Discovery® MR450.

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

Mr. Ruoqian Liu
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CHINA

Re: K103330
Trade/Device Name: Brivo MR355/Optima MR 360
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and LNI
Dated: January 20, 2011
Received: January 20, 2011

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Dear Mr. Liu:

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 Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103330

Device Name: Brivo MR355/Optima MR360

Indications for Use:

The Brivo MR355/ Optima MR360 is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Brivo MR355/ Optima MR360 reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use X **AND/OR** **Over-the-Counter Use** _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mary S Pastel

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

510K K103330