K112002

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NOV 18 2011

510(k) Summary of Safety and Effectiveness

Submitter: Shanghai Chenguang Medical Technologies Co., Ltd

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Date Summary Prepared: May 26, 2011

Reason for 510(K): New Device
Classification Name: Magnetic Resonance Diagnostic Device
Classification Panel: Radiology
Classification Number: 892.1000
Product Code: MOS
Common Name: Magnetic Resonance Imaging Coil
Proprietary Name: Carotid Coil
Establishment Registration Number: 3006239787
Regulatory Class: II

Predicate Devices (Legally Marketed Devices)

Carotid Coil, manufactured by Shanghai Chenguang Medical Technologies Co., Ltd.

510k number is K092962.

Device Description

Carotid Coil is a phased array, receive-only coil. It consists of eight elements optimized for high signal-to-noise ratio. Semi-flexible design makes the coil reliable and comforts the patient. The devices are as follows:

Coil type	Part number	Compatible system	Field strength
Carotid Coil	5000011501 or 0200130101	GE	3T
	5000011401 or 0300190101	Siemens	3T
	5000021901 or 0100450201	Philips	1.5T
	5000002201 or 0200120201	GE	1.5T
	5000022001 or	Siemens	1.5T

	0300190201		

The enclosure of all the carotid coils above is the same. The enclosure, which may contact the patient, is made up of biocompatible material.

Intended Use

The carotid coil is a receive-only coil, used for high resolution imaging of the bifurcation of the carotid artery in 1.5T and 3T General Electric, Siemens and Philips Magnetic Resonance Imaging (MRI) systems.
Nucleus Excited: Proton 1H
Anatomic regions: Carotid.

Indications for Use:

The Carotid Coil is used for obtaining diagnostic images of carotid in magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Comparison with Predicate Device:

Carotid Coil is similar to the Shanghai Chenguang Medical Technologies Co., Ltd. made predicate device in all aspects as follow:

Intended use- The carotid coil is a receive-only coil, used for high resolution imaging of the bifurcation of the carotid artery in 1.5T and 3T General Electric, Siemens and Philips Magnetic Resonance Imaging (MRI) systems.
Anatomic regions: Carotid.

Indication for use- The Carotid Coil is used for obtaining diagnostic images of carotid in magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Technical Characteristics-The MR system is an imaging device. The fundamental scientific technology of a radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest. It is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation.
The fundamental scientific technology of the subject device is the same as the predicate device.

Suitable standards - UL 60601-1, ISO 10993-5 and ISO 10993-10.

Conclusions

The submitted Carotid Coil has been proved to be safe and effective by performance tests, bio-compatibility tests and IEC60601-1 compliance tests.

As stated above, Carotid Coil complies with the appropriate medical device standards and is substantially equivalent to the predicate device in safety and effectiveness based on similarities in design features, overall indications for use, and technological characteristics.

It is the opinion of Shanghai Chenguang Medical Technologies Co. LTD. that the Carotid Coils are substantially equivalent to Shanghai Chenguang Medical Technologies Co. LTD. made Carotid Coil (K092962). Testing and usage of the Carotid Coils do not result in any new potential hazards.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Mr. Meijuan Chen
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CHINA

NOV 18 2011

Re: K112002
Trade/Device Name: Magnetic Resonance Diagnostic Device, Carotid Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 14, 2011
Received: November 14, 2011

Dear Mr. Chen:

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

Section 3

Indications for Use

510(k) Number (if known): K112002

Device Name: Magnetic Resonance Diagnostic Device, Carotid Coil

Indications for Use: The Carotid Coil is used for obtaining diagnostic images of carotid in magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

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

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

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

- End of Section -

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

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