K092962

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510(k) Summary of Safety and Effectiveness

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Date Summary Prepared: Apr 10, 2009

OCT - 9 2009

Device Name: Carotid Coil
Applicability: Compatible with PHILIPS 3.0T System
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: Model 5000004901 Carotid Coil
Establishment Registration Number: 3006239787
Regulatory Class: II

Predicate Devices (Legally Marketed Devices)

The predicate device for the Carotid Coil is the Machnet Carotids Coil Array Assembly from Machnet B.V., with the 510k number of K012491.

Device Description

The Carotid Coil is an 8-channel phased array, receive-only coil, used for obtaining diagnostic images of carotid in magnetic resonance imaging systems. These images, when interpreted by a trained physician, yields information that may assist in diagnosis.

Intended Use

Diagnostic Uses: 2D, 3D imaging, proton density, T1 and T2 weighted imaging. 2D, 3D time of flight, phase contrast imaging.

Anatomic regions: carotid.

Comparison with Predicate Device:

The Carotid Coil and the predicate device has the similar intended use, work in the similar principle, is compliant with the similar standards and is of the similar safety and effectiveness.

K092962

Conclusions

The submitted Carotid Coil have been proved to be safe and effective by safety tests, performance tests, bio-compatibility tests, practical application tests and IEC60601-1 compliance tests. All the tests results are available in section 10 of this submission.

As stated above, the Carotid Coil, comply with the appropriate medical device standards and are as safely and effectively substantially equivalent to the earlier identified predicate devices.

- End of Section -

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

Shanghai Chenguang Medical Technologies Co., Ltd.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

OCT - 9 2009

Re: K092962
Trade/Device Name: Magnetic Resonance Diagnostic Device, 5000004901, Carotid Coil
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: MOS
Dated: September 18, 2009
Received: September 25, 2009

Dear Mr. Conry:

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 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092962

Section 3 Indications for Use

510(k) Number (if known): K092962

Device Name: Magnetic Resonance Diagnostic Device, 5000004901, Carotid Coil

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

- End of Section -

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092962