K101858

JUL 14 2010

** This document can be copied and submitted to interested parties as required by 21 CFR 807.92.*

510(k) Summary of Safety and Effectiveness

Submitter: Shanghai Chenguang Medical Technologies Co., Ltd

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Date Summary Prepared: May 25, 2010

Device Name: Pediatric Head-Spine Coil (Model: 5000012701)
Applicability: Compatible with PHILIPS ACHIEVA 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: Pediatric Head-Spine Coil (Model: 5000012701)
Establishment Registration Number: 3006239787
Regulatory Class: II

Predicate Devices (Legally Marketed Devices)

Pediatric Head-Spine Coil, manufactured by Shanghai Chenguang Medical Technologies Co., Ltd.

510k number is K081322.

Device Description

The Pediatric Head-Spine Coil is an 8-channel phased array, receive-only coil. It consists of eight elements optimized for high signal-to-noise ratio. Four elements are in the head area and four elements reside in the back portion of the device. It includes two parts (upper part and the bottom). The upper part can be easily taken down from the bottom. So the Pediatric Head-Spine Coil could be operated expediently. The enclosure is 3.5mm thick PC, which is UL 94V_0 rated and can withstand highest peak RF voltage up to 4200V and drop and impact.

Intended Use

The Pediatric Head-Spine Coil is a receive-only coil, used for obtaining diagnostic images of pediatric head and spine in magnetic resonance imaging systems. These images when interpreted by a trained physician, yielding information that may assist in diagnosis.

Anatomic regions: Head-Spine of a pediatric body.

Indications for Use:

The Pediatric Head-Spine Coil is a receive-only coil, used for obtaining diagnostic images of pediatric head and spine in magnetic resonance imaging systems. This coil is designed to be used in a Philips Achieva MRI 3.0T system. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Comparison with Predicate Device:

Pediatric Head-Spine Coil is identical to the predicate device. They have the similar intended use, work in the similar principle, are compliant with the similar standards and are of the similar safety. The difference is the applicable system. The predicate device is compatible with 1.5T system, while the submitted device is compatible with 3.0T system. The different applicable system will not result in big difference in their effectiveness. So the submitted Pediatric Head-Spine Coil does not result in any new potential hazards.

Conclusions

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

As stated above, Pediatric Head-Spine Coil complies with the appropriate medical device standards and is substantially equivalent to the predicate device in safety and effectiveness.

- 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

JUL 14 2010

Shanghai Chenguang Medical Technologies Co., Ltd.
% Mr. Mark M. Mouser
Manager & FDA Office Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K101858
Trade/Device Name: Magnetic Resonance Diagnostic Device, Pediatric Head-Spine Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 23, 2010
Received: July 2, 2010

Dear Mr. Mouser:

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,

Donald J. St.Pierre
Acting 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): _____

Device Name: Magnetic Resonance Diagnostic Device, Pediatric Head-Spine Coil (Model: 5000012701)

Indications for Use: The Pediatric Head-Spine Coil is a receive-only coil, used for obtaining diagnostic images of pediatric head and spine in magnetic resonance imaging systems. This coil is designed to be used in a Philips Achieva MRI 3.0T system. 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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