K081322

JUN 18 2008

** 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: International Regulatory Consultants

For: Shanghai Chenguang Medical Technologies Co., Ltd

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Company Contact: Songtao Zhang

Date Summary Prepared: April 5, 2008

Device Name

Trade Name: Pediatric Head and Spine Array Coil1.5T 8ch
Common Name: Pediatric Head and Spine Array Coil
Classification Name: 892.1000 Magnetic Resonance Diagnostic Device
Classification: Class II

Predicate Devices (Legally Marketed Devices)

A predicate device for the 0100140201 Pediatric Head Spine coil 1.5T is the PHS-63 Pediatric Head Spine Coil, manufactured by MRI Devices Corporation and cleared under K003655.

Device Description

The Model 0100140201 Pediatric Head and Spine Array Coil1.5T 8ch consists is a single unit with eight coils. Four coils are in the head area and four coils reside in the back portion of the device. This forms a 8-channel phased array, receive-only coil, used for obtaining diagnostic images of head and spine of a pediatric body in magnetic resonance imaging systems. Combination of back part and head part forms an 8-channel phased array, receive-only coil, used for

obtaining diagnostic images of the head and spine in magnetic resonance imaging systems. These images when interpreted by a trained physician, yielding information that may assist in diagnosis.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2008

Shanghai Chenguang Medical Technologies
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K081322
Trade/Device Name: Magnetic Resonance Diagnostic Device, Model 0100140201, Pediatric Head-Spine Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 2, 2008
Received: June 3, 2008

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): _____

Device Name:
Magnetic Resonance Diagnostic Device, Model 0100140201, Pediatric Head-Spine Coil

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 1.5T 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 Device Evaluation (ODE)

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- End of Section -

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081322