

JUL 28 2010

K101949

*\* 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

**Address:** Building 8, Lane 1199, Jidi Road, Shanghai, P.R.C. 201107

**Company Contact:** Jie Huang

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**Date Summary Prepared:** Feb 2, 2010

**Device Name:** Pediatric Body-Cardiac Coil (Model: 5000012601)

**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 Body-Cardiac Coil (Model: 5000012601)

**Establishment Registration Number:** 3006239787

**Regulatory Class:** II

**Predicate Device (Legally Marketed Device)**

Pediatric Body-Cardiac Coil, manufactured by Shanghai Chenguang Medical Technologies Co., Ltd.

510k number is K081340.

**Device Description**

The Pediatric Body-Cardiac Coil is a phased-array receive-only coil. It consists of eight elements optimized for high signal-to-noise ratio. It includes two parts (upper part and the bottom). The upper part can be easily taken down from the bottom. So the Pediatric Body-Cardiac 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 Cardiac Body Coil is a receive-only coil, used for obtaining diagnostic images of pediatric body and cardiac regions in magnetic resonance imaging systems. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Anatomic regions: Cardiac Body areas of a pediatric body.

**Indications for Use**

The Pediatric Body-Cardiac Coil is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in Philips Achieva 3.0T magnetic resonance imaging systems. These images when interpreted by a trained physician, yielding information that may assist in diagnosis.

**Comparison with Predicate Device:**

Pediatric Body-Cardiac 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 Body-Cardiac Coil does not result in any new potential hazards.

**Conclusions**

The submitted Pediatric Body-Cardiac 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 Body-Cardiac 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

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

**JUL 28 2010**

Re: K101949

Trade/Device Name: Magnetic Resonance Diagnostic Device, Pediatric Body-Cardiac Coil  
(Model: 5000012601)

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: MOS

Dated: June 24, 2010

Received: July 12, 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.

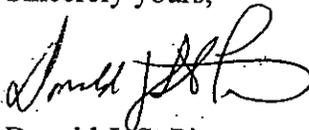
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

JUL 28 2010

Section 3

Indications for Use

510(k) Number (if known): 12101949

Device Name: Magnetic Resonance Diagnostic Device, Pediatric Body-Cardiac Coil  
(Model: 5000012601)

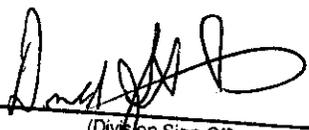
Indications for Use: The Pediatric Body-Cardiac Coil is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in Philips Achieva 3.0T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

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

(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 -

  
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(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K 12101949