K071847

Section 4 **510(k) Summary**

JUL 23 2007

Model: **CG-KFC18-H150-AP**

- 510(k) Summary of Safety and Effectiveness

** 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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Company Contact: Songtao Zhang

Date Summary Prepared: June.7th, 2007

Device Name: Knee/Foot/Ankle Coil

Applicability: Compatible with PHILIPS Intera+Achieva 1.5T System

Reason for 510(K): New Device

Classification Name: Magnetic Resonance Diagnostic Device

Classification Panel: Radiology

Classification Number: 892.1000

Product Code: 90MOS

Common Name: Magnetic Resonance Imaging Coil

Proprietary Name: Model CG-KFC18-H150-AP Knee/Foot/Ankle Coil

Establishment Registration Number: 3006239787

Regulatory Class: II

Predicate Devices (Legally Marketed Devices)

The predicate devices for the Knee-Foot-Ankle coil 4ch 1.5T are the 473PH-64Quadrature lower extremity coil,with 510(k) number of K991724, Model 1300GE-64 - Pediatric Positioner with 510(k) number of k030317 and Model PHS-63 Pediatric Head and Spine Array Coil with 510(k) number of k003655.

Device Description

The Knee/Foot/Ankle Coil consists of three parts, bottom part with a cable and a base plate, a knee part and a foot part. The combination of the bottom part and knee part forms a 4-channel phased array, receive-only coil, used for obtaining diagnostic images of knee, foot, ankle and lower leg in magnetic resonance imaging systems.

Combination of bottom part and foot part forms a 4-channel phased array, receive-only coil, used for obtaining diagnostic images of foot and ankle. 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 in conjunction with a PHILIPS 1.5T MRI scanner.

Anatomic regions: knee, foot ankle and lower leg

Comparison with Predicate Device:

The Knee/Foot/Ankle Coil has similar intended use with the predicate 473PH-64Quadrature lower extremity coil, Model 1300GE-64 - Pediatric Positioner and Model PHS-63 Pediatric Head and Spine Array Coil. They work in the similar principle, are compliant with the similar standards and are of the similar safety and effectiveness.

Summary of Performance Testing

The primary performance of MRI coil including signal to noise ratio and uniformity of images are tested and compared with the predicate 473PH-64Quadrature lower extremity coil. The signal to noise ratio is same as or better than this predicate device and the uniformity is similar to this predicate device.

Conclusions

As stated above, the Knee/Foot/Ankle Coil□Model CG-KFC18-H150-AP are safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the predicate devices.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 23 2007

Shanghai Chenguang Medical Technologies Co., Ltd.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K071847
Trade/Device Name: Magnetic Resonance Diagnostic Device, CG-KFC18-H150-AP, Knee/Foot/Ankle Coil
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 3, 2007
Received: July 5, 2007

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 (Premarket Approval), 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 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" (21 CFR 807.97). 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) 443-6597 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

510(k) Number (if known): K071847

Device Name: Magnetic Resonance Diagnostic Device, CG-KFC18-H150-AP□
Knee/Foot/Ankle Coil

Indications for Use:

The Knee/Foot/Ankle Coil is a receive-only coil, used for obtaining diagnostic images of knee, foot, ankle and lower leg in conjunction with a PHILIPS 1.5T MRI scanner. These images when interpreted by a trained physician, yielding 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)

- End of Section -

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071847