K 123238

FEB 2 5 2013

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 12, 2012
Submitter:	GE Healthcare, （GE Medical Systems (China) Co., Ltd) No.19, Changjiang Road, Wuxi National Hi-Tech Development Zone, Jiangsu, China
Primary Contact Person:	Liu Zhao Regulatory Affairs Leader GE Healthcare, (GE Medical Systems (China) Co., Ltd) (+86 510) 85278028 (+86 510) 85226891
Secondary Contact Person:	Trishia Dwyer Regulatory Affairs Leader GE Healthcare Telephone: (608) 221-1551 x 500-3074 Fax: (608) 646-6488
Device: Trade Name:	Achilles
Common/Usual Name:	Achilles OsteoReportN
Classification Names:	21CFR892.1180, Class II
Product Code:	MUA
Regulation Description:	A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. The primary components of the device are a voltage generator, a transmitting transducer, a receiving transducer, and hardware and software for reception and processing of the received ultrasonic signal.
Secondary Product Code:	LLZ
Secondary Regulation Description:	A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

Predicate Device(s): Achilles EXP II

Device Description: Achilles OsteoReportN is a software program running on PC to enter patient information, remote control and retrieve measurement results of GE ultrasonometer to help physicians to analysis the osteoporotic fracture risk and communicate with hospital information system.

Achilles ultrasonometers measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index.

The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip.

Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by x-ray absorpiometry. Either the stiffness index t-score or x-ray absorptiometry t-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment.

The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.

Achilles OsteoReportN is a windows based application running on PC and will provide the following capabilities for Achilles series device:

1) A patient database
2) Customizable reporting
3) Operation of the Achilles unit from the PC to provide ergonomic relief to the operator
4) Communication to the hospital/clinic information system

The objectives of this program including:

- Support Windows 7 (64 bit)/Windows XP(32bit) operating system
- Support merging the database with older version of Achilles product with the database used with the newer Achilles ultrasonometers, which is stored on the device.
- Support remote control of EXPII's measurement and retrieve measurement results
- Support customized report printing
- Support DICOM

This software does not change the intended use of Achilles series device.

Intended Use: Achilles OsteoReportN is PC-based software used with the Achilles family of ultrasonometers to provide a patient database, customized reporting, and communication with Health Information Systems. Achilles OsteoReportN together with the Achilles ultrasonometers measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index.

The Stiffness Index indicates risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip. Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by x-ray absorpiometry. Either the stiffness index t-score or x-ray absorptiometry t-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment.

The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.

Technology: Achilles OsteoReportN employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:
The Achilles OsteoReportN and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:
The subject of this premarket submission, Achilles OsteoReportN, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Achilles OsteoReportN to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 25, 2013

GE Medical Systems China Co., Ltd.
c/o Mr. Liu Zhao
Regulatory Affairs Leader
No 19 Changjang Road, National Hi-Tech Dev. Zone
Wuxi, Jiangsu, 214028
CHINA

Re: K123238
Trade/Device Name: Achilles OsteoReportN
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone sonometer
Regulatory Class: Class II
Product Code: MUA, LLZ
Dated: January 11, 2013
Received: January 16, 2013

Dear Mr. Zhao:

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.

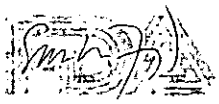
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,



for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K123238
Device Name: Achilles OsteoReportN

Indications for Use
Achilles OsteoReportN is software used with the Achilles family of ultrasonometers to provide a patient database, customized reporting, and communication with Health Information Systems. Achilles OsteoReportN together with the Achilles ultrasonometers measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index.

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K123238

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