K080048
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510(k) Summary

Submitter:
ONI Medical Systems, Inc.
301 Ballardvale Street, Suite 4
Wilmington, MA 01887
USA

FEB - 6 2008

Contact Person:
Mark Puopolo
Quality Assurance/Regulatory Affairs Manager
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Date Prepared:
January 4, 2008

Trade Name:
MSK Extreme™ MRI Scanner

Common Name:
Magnetic Resonance Diagnostic Device

Classification Name:
Magnetic Resonance Diagnostic Device

Predicate Device:
OrthOne Extremity MRI Scanner (K001773)
Philips Medical Systems Achieva 1.5T(K052013)
MAGNETOM Systems with Software syngo MR 2006A (1.5T Symphony version) (K052164)

Device Description:
The MSK Extreme™ MR Scanner utilizes a superconducting magnet to acquire 2D single-slice and multi-slice and 3D volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, fast spin echo, 2D and 3D gradient echo acquisitions. Imaging options such as inversion recovery, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality. The system is used as a stationary system.

Statement of Intended Use:
The MSK Extreme™ MR Scanner is intended for use as a diagnostic imaging device to produce axial, sagittal, coronal and oblique images of the internal structures of the leg (excluding the thigh), knee, ankle, foot, forearm, elbow, wrist and hand.

Summary of Technological Characteristics:	In addition to being technologically equivalent to the predicate devices, the MSK Extreme™ MR Scanner has been subjected to performance testing and it has been determined that the MSK Extreme™ MR Scanner is suitable for its intended use.
Summary of Non-clinical Data:	The MSK Extreme™ MR Scanner is manufactured under the same conditions, using the similar processes and equivalent materials, as the ONI OrthOne Extremity MRI Scanner, the legally marketed ONI predicate device. In addition to being technologically equivalent, the indications for use have not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Mr. Mark Puopolo
Quality Assurance/Regulatory Affairs Manager
ONI Medical Systems, Inc.
301 Ballardvale Street, Suite 4
WILMINGTON MA 01887-4405

Re: K080048
Trade/Device Name: MSK Extreme™ MRI Scanner
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 4, 2008
Received: January 8, 2008

Dear Mr. Puopolo:

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

ONI Medical Systems, Inc.

Indications for Use

510(k) Number (if known): K080048

Device Name: MSK Extreme™ MRI Scanner

Indications: The ONI MSK Extreme™ MR Scanner is indicated to use as a magnetic resonance imaging device of the leg (excluding the thigh), knee, ankle, foot, elbow, forearm, wrist, and hand. The device produces transverse, sagittal, coronal, and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. If interpreted by a medical expert, these images can provide diagnostically useful information.

Prescription Use X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080048