K091580

Section XI 510(k) Summary

JUL 24 2009

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____

Date of Submission: March 9, 2009

Sponsor:
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Proposed Device

Trade Name	Pica Whole Body MRI System
Model:	TMS-MRI-3000WB-01
Classification Name:	System, Nuclear Magnetic Resonance Imaging
Product Code:	LNH
Regulation Number:	892.1000
Device Class:	II

Predicate Device: mStar MPF4500 **(K073457)**

Intended Use: PICA is indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Pica may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

Device Description: Pica Whole Body MRI System is a 0.3T permanent magnet MRI system. It is composed of Magnet, Magnet Enclosure, Patient Table, Gradient Coil, RF Transmission Coil, RF Receiver Coil, Client PC, and Imaging Cabinet. The system software, PRODIVA, based on Windows XP® Professional is aninteractive program with user friendly interface.

Testing Conclusion: Performance testing including clinical and laboratory testing was conducted to validate and verify that the proposed device, Pica Whole Body MRI System met all design specifications and was substantially equivalent to the predicate device.

SE Conclusion: Pica Whole Body MRI System, is claimed to be Substantially Equivalent (SE) to the predicate device, mStar MPF4500 (K073457)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Time Medical Limited
% Mr. Morten Simon Christensen
Asst. Manager, Program Reviewer
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

JUL 24 2009

Re: K091580
Trade/Device Name: Pica Whole Body MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 17, 2009
Received: July 22, 2009

Dear Mr. Christensen:

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit #B Indication for Use Form

510(k) Number: K091580
Device Name: Pica Whole Body MRI System

Indications for Use:

PICA is indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Pica may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091580