K093984

Section VIII 510(k) Summary

MAR 24 2010

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

Date of Submission:	December 23, 2009
Sponsor:	**Time Medical Limited** G/F Bio-Informatics Centre, No. 2 Science Park West Avenue, Hong Kong Science Park, Shatin, New Territories, Hong Kong, China Contact Person: Johnson Chong, VP Product Development
Correspondent:	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 8D, No. 19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China
Proposed Device	Pica Whole Body MRI System TMS-MRI-3500WB-01
Classification Name:	System, Nuclear Magnetic Resonance Imaging
Classification	Class II / LNH / 892.1000
Predicate Device:	Pica Whole Body MRI System TMS-MRI-3000WB-01 **(K091580)**
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 0.35T 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. It is a modified system to the existed and cleared Pica Whole Body MRI System (K091580), in Magnet (Static Field Strength), Appearance, Receive Coil and some specifications.
Testing Conclusion:	Performance 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, Pica Whole Body MRI System (K091580).

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

Time Medical Limited
% Ms. Diana Hong
Submission Correspondent
Shanghi Mid-Link Business Consulting Co., Ltd
Suite 5D, No. 19, Lane 999, Zhongshan Road (S-2)
Shanghai, 200030
CHINA

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Re: K093984
Trade/Device Name: Pica Whole Body MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 1, 2010
Received: March 2, 2010

Dear Ms. Hong:

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.

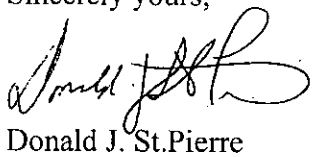
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Indications for Use

510(k) Number (if known): **k093984**

Device Name: Pica Whole Body MR System

Indications for Use:

"Pica Whole Body MRI System, TMS-MRI-3500WB-01, 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.

It may 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 ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K093984