K112293

SEP 30 2011

Attachment 2

510 (k) Summary

2.1 SUMMARY

Comparison Element	Filing Device		Predicate Device	
510(k) Number	TBD		K092230 (Mona Orthopedic MRI System)	K022863
Product Code	MOS		(an accessory of LNH)	MOS
Applicant	Time Medical		Time Medical	University of Hong Kong
Regulation Number	892.1000		892.1000	892.1000
Panel	Radiology		Radiology	Radiology
Class	Class II		Class II	Class II
Device Name (Model Number)	HTS Surface Coil (TM-HTS-SF001-0R35) , HTS Extremity Coil (TM-HTS-KN001-0R35)		HTS Coil as Accessory of the MONA MRI System	HTS Coil (HTS Coil)
Characteristics	**HTS Surface Coil**	**HTS Extremity Coil**	**K092230**	**K022863**
Intended Use	HTS Surface Coil is used to image peripheral anatomies, such as, wrist, ankle, Temporo-mandibular Joints (TMJ), Eye, finger and other parts of the body, close to the surface of skin. It is compatible to be used with Time Medical's 0.35T PICA Whole Body MRI System.	HTS Extremity Coil is predominantly used for imaging anatomies, such as, knee, ankle, and wrist. It is compatible to be used with Time Medical's 0.35T PICA Whole Body MRI System.	HTS Surface Coil is used to image peripheral anatomies such as, Wrist, Ankle, TMJ, Eye, Finger and other parts of the body, close to the surface of the skin.	MRI surface coil for peripheral anatomical imaging Anatomical region: Temporo-mandibular joint (TMJ), wrist and other anatomies that are no deeper than 1.5 inches from the skin.
Applicable Systems	Time Medical, Pica Whole-body MRI System	Time Medical, Pica Whole-body MRI System	Time Medical, Mona Orthopedic MRI System	GE 0.2T Signa Profile MRI System
Mode of Operation	Single-Channel	Single-Channel	Single-Channel	Single-Channel
Coil Configuration (Linear, Quad, array, etc)	Single Channel surface coil	Single Channel Volume coil	Single Channel surface coil	Single Channel surface coil

Safety				
SAR (T/R Coils)	N/A, Receive Only Coil	N/A, Receive Only Coil	N/A, Receive Only Coil	N/A, Receive Only Coil
Power Input Protection (T/R Coils)	N/A, Receive Only Coil	N/A, Receive Only Coil	N/A, Receive Only Coil	N/A, Receive Only Coil
Material	ABS	ABS	ABS	PVC

Technological				
	Filing Device:		Predicate Device:	
Parameter	HTS Surface Coil	HTS Extremity Coil	HTS Coil as Accessory of K092230 (Mona Orthopedic MRI System)	HTS Coil (K022863)
T/R	Receive-Only	Receive-Only	Receive-Only	Receive-Only
Coil Type	Single Channel Surface Coil	Single Channel Volume Coil	Single Channel Surface Coil	Single Channel Surface Coil
Cooling liquid	LN2 (Liquid Nitrogen)	LN2 (Liquid Nitrogen)	LN2 (Liquid Nitrogen)	LN2 (Liquid Nitrogen)

2.2 GENERAL SAFETY AND EFFECTIVENESS

The technological characteristics of Time Medical's HTS Surface Coil and HTS Extremity Coil are similar to the predicate device. They work on the same principle, have similar design, are constructed of similar materials and are of similar safety and effectiveness.

It does not induce other safety issues and warning than already valid for the current cleared RF external coils.

2.3 SUBSTANTIAL EQUIVALENCE

The HTS Surface coil and the HTS Extremity Coil are substantially equivalent to the other HTS coil(s) which has been cleared for commercial distribution as part of Time Medical Limited's MONA Orthopedic MRI System (ref. K092230), and the HTS coil of University of Hong Kong (K022863).

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 Systems, Inc.
% Mr. John Baby
Director-Regulatory Affairs
Time Medical Limited, G/F Bio-Informatics Centre
No. 2 Science Park West Avenue
Hong Kong Science Park, Shatin, New Territories,
Hong Kong CHINA

SEP 30 2011

Re: K112293
Trade/Device Name: HTS Surface Coil, HTS Extremity Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 1, 2011
Received: August 10, 2011

Dear Mr. Baby:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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):

Device Name: HTS Surface Coil, HTS Extremity Coil

Indications for Use:
HTS Surface Coil is used to image peripheral anatomies, such as, wrist, ankle, Temporo-mandibular Joints (TMJ), Eye, finger and other parts of the body, close to the surface of skin. It is compatible to be used with Time Medical's 0.35T PICA Whole Body MRI System.

HTS Extremity Coil is predominantly used for imaging anatomies, such as, knee, ankle, and wrist. It is compatible to be used with Time Medical's 0.35T PICA Whole Body MRI System.

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)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112293