2.1 SUMMARY

<table>
<thead>
<tr>
<th>Comparison Element</th>
<th>Filing Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>TBD</td>
<td>K092230 (Mona Orthopedic MRI System)</td>
</tr>
<tr>
<td>Product Code</td>
<td>MOS</td>
<td>MOS (an accessory of LNH)</td>
</tr>
<tr>
<td>Applicant</td>
<td>Time Medical</td>
<td>Time Medical</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>892.1000</td>
<td>University of Hong Kong</td>
</tr>
<tr>
<td>Panel</td>
<td>Radiology</td>
<td>Radiology</td>
</tr>
<tr>
<td>Class</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Device Name (Model Number)</td>
<td>HTS Surface Coil (TM-HTS-SF001-0R35), HTS Extremity Coil (TM-HTS-KN001-0R35)</td>
<td>HTS Coil as Accessory of the MONA MRI System</td>
</tr>
<tr>
<td>Characteristics</td>
<td>HTS Surface Coil</td>
<td>HTS Extremity Coil</td>
</tr>
<tr>
<td>Intended Use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Applicable Systems</td>
<td>Time Medical, Pica Whole-body MRI System</td>
<td>Time Medical, Pica Whole-body MRI System</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Single-Channel</td>
<td>Single-Channel</td>
</tr>
<tr>
<td>Coil Configuration (Linear, Quad, array, etc)</td>
<td>Single Channel surface coil</td>
<td>Single Channel volume coil</td>
</tr>
</tbody>
</table>
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).
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

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, 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, Temporomandibular 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)

[Signature]

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

510(k) Number K12293