K130692
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510(k) Summary of Safety & Effectiveness

JAN 14 2014

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	Aspect Imaging, Ltd. 27 Shaked Street Industrial Area Hevel Modi'in Shoham, Israel 60850
	Mfg. Phone:	Tel.: +972 73 2239000
	Contact Person:	Uri Hoffer
	Date:	December 1, 2013
2.	***Device & Classification:***	Magnetic Resonance Imaging System have been classified as Class 2 LNH, Regulation Number 21 CFR 892.1000 Magnetic resonance diagnostic device
	Name:	M2 Wrist 2 MRI System
3.	***Predicate Device:***	M2 Wrist MRI System K120701
4.	***Description:***	The M2 Wrist 2 MRI System is a 1 Tesla, compact, high-performance solution, based on a permanent magnet. Due to its remarkable structure, the external magnetic field is very low, thus offering unique safety advantage. The system has very low Eddy currents and exhibits very low gradient-related acoustic noise. The magnet is self-shielded and thus no RF shielded room is required. The type of installation is fixed.

The M2 Wrist 2 MRI System's main components are:

- Magnet Sub-system
- Wrist Coil
- Electronics Cabinet
- Aspect Imaging Proprietary Software
- Computer
- Isolation Transformer

Specific Technical Description: see below in Section 6

5. ***Intended Use:*** The **M2 Wrist 2 MRI System** is indicated for use as a magnetic resonance imaging device for producing transverse, sagittal and coronal images of the internal structure of the wrist (in patients with an arm length > 320mm). When interpreted by a trained physician, the resultant MR images provide information that can be useful in determining a diagnosis.

6. ***Technology:*** Technology and Comparison of Characteristics

With respect to technology and intended use, the M2 Wrist 2 MRI System is substantially equivalent to its predicate device which is the M2 Wrist MRI System. The primary differences are the addition of plastic panels, modified wrist coil, a change in the spectrometer, additional pulse sequences and added MRI viewing features. Based upon the validation results, Aspect Imaging believes these changes do not raise additional safety of efficacy concerns.

Characteristic / Feature	**Predicate Device (System)**	**Modified Device (System)**
Magnet Subsystem		
Field Strength	1.05 (+/- 2%) Tesla vertical field	1.05 (+/- 2%) Tesla horizontal field
Bore Opening Size (H x W)	76 x 200 mm	same
Field of View	115 x 80 x 50 mm	110 x 80 x 50 mm
Gradient System Type	Special purpose gradient system	same
Gradient Strength	190 mT/m	same
Slew Rate	400 T/m/sec	same
Rise Time	475 µsec	same
Gradient Amplifier Gain Scale	± 10 A output per ± 1 V input	same
Acoustic Noise	<75db	same
Cooling	Built-in cooling fans for magnet and gradient subsystem	same
Wrist RF Coil		
Central Frequency	45 MHz	same
Solenoid (9 turns)	yes	same
B 1 Direction	yes	same
Coil Housing Material	Ultralloy 910-5 GLU	Ultralloy 304
Balance Matching Circuit	yes	yes
Tuning Capacitor	yes	yes
Maximum RF peak handling	500 W	same
Topology	Transmit/Receive Coil	same

	Solenoid	
Electrical	Central Frequency: 45 MHz typical No decoupling circuits	same
Dimensions of Magnet sub-system	Height = 114 cm Width = 79 cm Length = 79 cm Weight = Approx. 930 kG	Height = 125 cm Width = 87 cm Length = 82 cm Weight = Approx. 1050 kG
Wrist Coil Dimensions & Positions	The maximum hand size that can be scanned is: Width: 108 mm Length: 210 mm Height: 50 mm	The maximum hand size that can be scanned is: Width: 108 mm Length: 220 mm Height: 50 mm
	Electronics Cabinet	
RF Power Amplifier	Tomco	same
Control Unit	Aspect	same
Gradient Amplifier	Copley	same
Power Distribution Unit	Aspect	same
Spectrometer	Tecmag-Apollo	Tecmag-Redstone
Dimensions of Electronics Cabinet	Height: 130 cm Width: 60 cm Length: 80 cm Weight: Approx. 205 kg	same
	Isolation Transformer	
Input	200-240 VAC 50/60 Hz	same
Output	200-240 VAC 9A, 2.16 kVA	same
Operator Emergency Stop Switch	yes	same
Main Circuit Breaker LED for Power Indication	yes	same
	Proprietary Software	
Software	Windows 7 Professional & Wrist MRI Software	same
Conventional MRI	2D Spin-Echo	2D Spin-Echo 2D Spoiled Gradient Echo

		3D Spoiled Gradient Echo 2D Fast Spin Echo 3D Fast Spin Echo Fat Suppression
Software Features	Perform MRI Scan Sequence parameter variability Multi-Slice 2D Viewer DICOM Export	same
Wrist MRI Software	Version 1.1	Version R.1.2.0.6
TNMR Software	Version 2.11.2	Version 2.11.22
	Computer	
Processor	Intel Xeon W3520 (2.66GHz,4.8GT/s,8 MB) Memory runs at 1066MHz	same
Resource DVD	Precision T3500 Diagnostics and Drivers	same
Memory	4GB (4x1GB)1066MHz DDR3 ECC-UDIMM	same
Hard Drive	2x320GB (7200RPM) Serial ATA II with NCQ and 16MB DataBurst Cache	same
Raid Controller	C1 All SATA Hard Drives, NON-RAID for 2 Hard Drive	same
Optical Drive	16X DVD+/-RW Drive; Power DVD 8.1 Software and Media included	same
Graphics	768 MB Quadro NVIDIA FX1800 - 2 DP, 1 DVI (1 DP-DVI,1 DVI-VGA adapter)	same
Operating System	English Windows 7 Professional with SP1	same

Though there are some minor differences in the characteristics of the two systems, these differences do not raise new questions of safety or efficacy. Furthermore, the M2 Wrist 2 MRI System has passed all the required tests and standards for MRI devices, as did the predicate M2 Wrist MRI System.

7. ***Performance Data Non-Clinical:***

Performance Standards:
The following performance tests were performed on the **M2 Wrist 2 MRI System** or its components:

- Electrical & Mechanical Safety **(IEC 60601 -1)**
- Electromagnetic Compatibility **(IEC 60601-1-2)**
- Software Validation
- MR Image Quality Testing
- **NEMA MS- 1-2008** Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- **NEMA MS 3-2008** Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images (Image Uniformity Test)
- **NEMA MIS 4 (2006)** Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- **NEMA MS 5-2010** Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- **NEMA MS 8 (2006)** Characterization of the Specific Absorption Rate (SAR) for MRI Systems
- **NEMA MS 10-2006** Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
- **NEMA MS 11 -2006** Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging
- **NEMA MS 12-2006** Quantification and Mapping of Geometric Distortion for Special Applications
- **IEC 60601-2-33** Medical electrical equipment - Part **2-33**: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic **(2007** (Second Edition) **+ Al 1:2005 ± A2:2007)**
- High Contrast Spatial Resolution Testing

In all instances, the **M2 Wrist 2 MRI System** functioned as intended and/or met the requirements of the standard

7. ***Clinical Performance Data:***

Not applicable

8. ***Conclusions:***

Conclusions Drawn from Non-Clinical and Clinical Tests
The performance tests demonstrate that M2 Wrist 2 MRI System may be safely and effectively used in acquiring wrist MR images. The software validation and performance tests demonstrate that the M2 Wrist 2 MRI System meets its design and performance specifications and is substantially equivalent to the cleared M2 Wrist MRI System.

8.	***Substantial Equivalence:***	In summary, the indications for use of the M2 Wrist 2 MRI System are the same and thus substantially equivalent to the M2 Wrist MRI System. Furthermore, the basic technological characteristics of the M2 Wrist 2 MRI System are similar to the predicate M2 Wrist MRI System. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the M2 Wrist 2 MRI System is substantially equivalent it's predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 14, 2014

Aspect Imaging Ltd.
% Mr. George Hattub
Senior Staff Consultant
MedicSence, USA
291 Hillside Avenue
SOMERSET MA 02726

Re: K130692
Trade/Device Name: M2 Wrist 2 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 1, 2013
Received: December 13, 2013

Dear Mr. Hattub:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130692

Device Name: M2 Wrist 2 MRI System

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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 Device Evaluation (ODE)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health/OIR
510(k) _____K130692_____