EMS9U: A 510k SUBMISSION Shenzhen Delicate Electronics Co. Ltd

K092164
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SUMMARY

MAY 13 2010

This summary of 510k safety and effectiveness information is being submitted in accordance with 21CFR part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

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518054 Nanshan District
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People's Republic of China
Phone: 086 0755-26412665
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Responsible person: Frank Qui

Official Correspondent:

William Stern
Multigon Industries, Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
Phone: 914 376 5200 X27
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Date of Preparation: April 7, 2009

2. Device:

Proprietary Name: EMS9UA Transcranial Doppler with Robotic Probe Headband

Common Name: Transcranial and Vascular Doppler Diagnostic Ultrasound Transducer
Classification Name: 21 CFR892.1550 System,Imaging,Pulsed Doppler, Ultrasonic
21 CFR892.1570 Diagnostic Ultrasound Transducer

Classification Number: 90IYN
90ITX

Manufactured By: Shenzhen Delicate Electronics Co. Ltd.
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Tian-an Ind. Area
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3. Substantially Equivalency

Device Description:

Shenzhen Delicate believes that the Model EMS-9UA is substantially equivalent to its EMS9U Transcranial Doppler which was cleared on May 5, 2006 510k# K060112. The EMS-9UA has the same device description except that the head frame used for longer term monitoring has the ability to track the Doppler signal and therefore not lose the signal with patient movement and time. The tracking is accomplished by adding to the EMS9U an additional circuit which detects the ultrasound Doppler return and positions the face of the probe in the headband to maximize the detected ultrasound return. The headband electronics does not change or interfere with the transmitted ultrasound. Except for the servo motor controller added to the circuitry of the EMS9U range and the software added to control it, and the modifications to the head frame to accommodate the servo motor controlled probe, the EMS9U range and the EMS- 9UA are identical internally and functionally. The probes are identical to those cleared in K060112.

Hence the EMS-9UA is substantially equivalent to the EMS9U range of Trans Cranial Dopplers.

Product Comparison Chart

Parameters	EMS9U range	EMS-9UA	SPENCER TCD 100M MARC 600
510k Number	K060112	K092164	K002533
Transducer Frequency	2,4, and 8 mHz	2,4, and 8 mHz	2 mHz
Frequency Spectrum	FFT256/512 dots	FFT256/512 dots	FFT256/512 dots
Frequency Ranges	1 to 16 mHz	1 to 16 mHz	2 mHz
Depth Measurement	5 to 136 mm	5 to 136 mm	5 to 140 mm
Gain	0 to 40 dB	0 to 40 dB	0 to 40 dB
Clinical Application For 2 mHz			
PWD	Opthalmic,Adult Cephalic & Peipheral Vascular	Opthalmic,Adult Cephalic & Peipheral Vascular	Opthalmic,Adult Cephalic
CWD	Opthalmic & Peripheral Vascular	Opthalmic & Peripheral Vascular	
Clinical Application For 4 mHz and 8 mHz CWD	Peripheral Vascular	Peripheral Vascular	
Head Frame	Bilateral Probes Adjusted Manually	Bilateral Probes Adjusted Manually and/or matically	Bilateral Probes Adjusted Manually

4. PERFORMANCE STANDARDS

No performance standards have been established for the EMS9UA Transcranial Doppler under section 514 of the Federal Food and Drug Act. However the EMS9UA Transcranial Doppler has been designed to meet the following standards:

UL 2601-1 Safety Requirements for Medical Equipment
AIUM/NEMA UD 2 Standard for Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
AIUM/NEMA UD 3 Standard for Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
IEC 1157 Declaration of Acoustic Power
IEC60601-1-2
IEC60601-2-37

5. INDICATIONS FOR USE

Indications for Use:
The EMS9UA Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:
1) For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values
2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.
The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal.
The EMS9UA Transcranial Doppler is intended for use during:
a) Diagnostic exams
b) Surgical interventions
The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

6. CONTRA-INDICATIONS

None known at this time.

7. COMPARISON TO PREDICATE DEVICES

The EMS9UA Transcranial Doppler has the same device characteristics as the approved predicate device listed above with the commonality of ultrasound transducers, principles of operation, and display of blood flow waveforms.

8. TEST DATA

The EMS9UA Transcranial Doppler with Robotic Probe Headband has been subjected to extensive safety, performance testing, and validation before release. Final testing of the EMS9UA included various performance tests designed to ensure that the device met all of its functional specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards.

A clinical trial involving 100 patients was conducted comparing the EMS9UA Transcranial Doppler with Robotic Headband with the Spencer Technologies Marc 600 predicate headband and was found to be safe and effective.

The Model EMS9UA Transcranial Doppler device labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. It has therefore shown to be safe and effective.

9. LITERATURE REVIEW

A review of the literature pertaining to the safety of the EMS9UA Transcranial Doppler has been conducted and appropriate safeguards have been incorporated in the design of the EMS9UA Transcranial Doppler.

10. CONCLUSIONS

The conclusion drawn from these tests is that the EMS9UA Transcranial Vascular Doppler with Robotic Probe Headband and it's transducers is substantially equivalent in safety and efficacy to the predicate devices listed in the comparison table above

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

MAY 13 2010

Shenzhen Delicate Electronics Co., Ltd.
% Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

Re: K092164
Trade/Device Name: EMS9UA Transcranial Doppler Robotic Probe Headband
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: OQQ, IYN and ITX
Dated: April 19, 2010
Received: April 21, 2010

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the EMS9UA Transcranial Doppler Robotic Probe Headband, as described in your premarket notification:

Transducer Model Number

2 MHz
4 MHz
8 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 market.

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/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Brendan O'Leary at (301) 796-6898.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K092164

Device Name: EMS9UA Transcranial Doppler with Robotic Probe Headband

Indications for Use:
The EMS9UA Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:
1) For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values
2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.
The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal.
The EMS9UA Transcranial Doppler is intended for use during:
a) Diagnostic exams
b) Surgical interventions
The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.
It is to be used by trained medical personnel in hospitals, clinics and physicians offices by prescription or doctor's orders.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Robert A. Becker
K092164

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

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APPENDIX G: DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FOR WHOLE

SYSTEM: EMS9UA TRANSCRANIAL DOPPLER K092164

INTENDED USE: diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

TRANSDUCER FREQUENCY	CLINICAL APPLICATION	MODE OF OPERATION	PREVIOUSLY CLEARED
2 MHZ	OPTHALMIC	PWD	K060112
2 MHZ	ADULT CEPHALIC	PWD	K060112
2 MHZ	PERIPHERAL VESSEL	PWD	K060112
4 MHZ	PERIPHERAL VESSEL	CWD	K060112
8 MHZ	PERIPHERAL VESSEL	CWD	K060112

PWD= PULSED WAVE DOPPLER

CWD=CONTINUOUS WAVE DOPPLER

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Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: EMS9UA Transcranial Doppler
Transducer: 2 mHz

Previously cleared under K060112 May 5 2006
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			P				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			P				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			P				
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: EMS9UA
Transducer: 4 mHz

Previously Cleared under K060112, May 5 2006
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				P			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: EMS9UA

Transducer: 8 mHz

Previously Cleared under k060112 May 5 2006

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				P			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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