Shenzhen Delica Medical Equipment Co., Ltd. July 11th, 2018
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K173801
Trade/Device Name: Transcranial Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, OQQ
Dated: June 12, 2018
Received: June 22, 2018

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. 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.

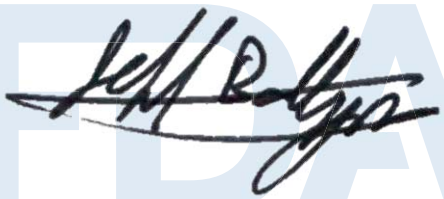
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173801

Device Name
Transcranial Doppler Ultrasound System

Indications for Use *(Describe)*
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 hemo dynamically 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.
Transcranial Doppler is intended for use during:
1) Diagnostic exams;
2) 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 1.6MHz PW Probe (02.0001.0170.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 1.6MHz PW Probe (AP99-0815-PW1.60)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 1.6MHz PW Probe (02.0001.1613.02)

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 (Track 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			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							
	Other (Specify)							

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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 2MHz PW Probe (02.0001.0214.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 4MHz CW Probe (02.0001.0408.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 8MHz CW Probe (02.0001.0805.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D

Transducer: 16MHz PW Probe (02.0128.1601.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9F

Transducer: 2MHz PW Probe (02.0001.0214.01)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9F

Transducer: 2MHz PW Probe (AP99-0607-PW2.0)

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 (Track 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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9F

Transducer: 2MHz PW Probe (02.0001.0213.01)

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 (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative(Specify)							
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	Laparoscopic							
	Pediatric							
	Small Organ(Specify)							
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	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							
	Other (Specify)							

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

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9F

Transducer: 4MHz CW Probe (02.0001.0408.01)

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 (Track 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)							

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K173801

1. Date of Preparation: 6/12/2018

2. Sponsor Identification

Shenzhen Delica Medical Equipment Co., Ltd.
6C, Block 10, The Second Industrial Zone, Guanlong, Nanshan District, Shenzhen 518055, China

Establishment Registration Number: 3006441164

Contact Person: Zhenhua Xiao
Position: Management Representative
Tel: +86-0755-26413482
Fax: +86-0755-86210002
Email: quality@delicasz.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China
Tel: +86(0)21 2281-5850
Fax: +1(0)360 925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Transcranial Doppler Ultrasound System;
Common Name: Transcranial Doppler;
Models: EMS-9D and EMS-9F

Regulatory Information
Classification: II
Product Code: IYN, ITX and OQQ;
Regulation Number: 21 CFR 892.1550 and 21 CFR 892.1570;
Review Panel: Radiology;

Indications for Use:
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 hemo dynamically 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.
Transcranial Doppler is intended for use during:

1) Diagnostic exams;
2) 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.

Device Description:
The EMS-9D/EMS-9F Transcranial Doppler Ultrasound System is a Transcranial Doppler (TCD) system using non-invasive technique to obtain the information of blood flow velocities throughout the body. This method of measurement is particularly useful for examining the major arteries supplying blood to the brain.

TCD is useful for evaluation of numerous neurological vascular diseases such as vasospasm and intracranial stenosis. TCD is also extremely valuable for intraoperative monitoring to help detect sudden changes in blood flow.

EMS-9D/EMS-9F should be used in hospitals or healthcare facilities by doctors or trained healthcare professionals.

5. Identification of Predicate Device

510k Number: K122710
Product Name: Transcranial Doppler with Robotic Probe Headband;
Manufacturer: Shenzhen Delicate Electronics Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.

IEC 60601-2-37:2007, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-1-2: 2007, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and teats.

NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3.

7. Substantially Equivalent

Table 1 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device, K122710
Product Code	IYN, ITX and OQQ	IYN, ITX and OQQ
Regulation No.	21 CFR 892.1550 and 21 CFR 892.1570	21 CFR 892.1550 and 21 CFR 892.1570
Class	II	II

<table>
<tr><td colspan="2">Intended Use</td><td colspan="2">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 hemo dynamically 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.
Transcranial Doppler is intended for use during:
1) Diagnostic exams;
2) 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.</td><td colspan="2">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 hemo dynamically 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.
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Transcranial Doppler is intended for use during:
1) Diagnostic exams;
2) 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.</td></tr>
<tr><td colspan="2" rowspan="2">Configuration</td><td colspan="2">EMS-9F: Main Unit+PC/Laptop+Transducer</td><td colspan="2">EMS-9UA: Main Unit+PC/Laptop+Transducer</td></tr>
<tr><td colspan="2">EMS-9D: Main Unit+Transducer</td><td colspan="2">EMS-9PB: Main Unit+Transducer</td></tr>
<tr><td colspan="2">Model</td><td>EMS-9D</td><td>EMS-9F</td><td>EMS-9PB</td><td>EMS-9UA</td></tr>
<tr><td colspan="2">Screen</td><td>15” LCD Display</td><td>No</td><td>15” LCD Display</td><td>No</td></tr>
<tr><td colspan="2">Nominal Voltage</td><td>AC 100V-240V</td><td>DC +12V, -12V, +5V</td><td>AC 100V-240V</td><td>DC +12V, -12V, +6V</td></tr>
<tr><td colspan="2">Nominal Frequency</td><td>50Hz/60Hz</td><td>/</td><td>50Hz/60Hz</td><td>/</td></tr>
<tr><td colspan="2">Input Power</td><td>80VA</td><td>60VA</td><td>275VA</td><td>30VA</td></tr>
<tr><td colspan="2">Probe</td><td>1.6/2/16MHz PW probe and 4/8MHz CW probe</td><td>2MHz PW probe and 4/8MHz CW probe</td><td>1.6MHz PW probe and 4/8MHz CW probe</td><td>2MHz PW probe and 4/8MHz CW probe</td></tr>
<tr><td colspan="6">Performance</td></tr>
<tr><td rowspan="3">1.6MHz PW</td><td>Depth</td><td>not less 150 mm</td><td>/</td><td>not less 134 mm</td><td>/</td></tr>
<tr><td>Speed range</td><td>10cm/s~300cm/s</td><td>/</td><td>20cm/s~200cm/s</td><td>/</td></tr>
<tr><td>Maximum Error</td><td>±15%</td><td>/</td><td>±20%</td><td>/</td></tr>
</table>

2MHz PW	Depth	not less 150 mm	not less 150 mm	not less 134 mm	not less 134 mm
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	20cm/s~200cm/s	20cm/s~200cm/s
	Maximum Error	±15%	±15%	±20%	±20%
4MHz CW	Depth	not less 85 mm	not less 85 mm	not less 50 mm	not less 50 mm
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	10cm/s~100cm/s	10cm/s~100cm/s
	Maximum Error	±15%	±15%	±20%	±20%
8MHz CW	Depth	not less 35 mm	/	not less 20 mm	not less 20 mm
	Speed range	10cm/s~200cm/s	/	10cm/s~50cm/s	10cm/s~50cm/s
	Maximum Error	±15%	/	±20%	±20%
16MHz PW	Depth	not less 8 mm	/	/	/
	Speed range	10cm/s~120cm/s	/	/	/
	Maximum Error	±15%	/	/	/

The main differences between proposed device and predicate device include nominal voltage, input power, probe and performance. Both proposed device and predicate device comply with IEC 60601-1, IEC 60601-2 and IEC 60601-2-37, they are identical in electrical safety and EMC. Compared with the predicate device, 16MHz PW probe are added in EMS-9D and 8MHz CW is removed in EMS-9F. Referring to the comparison table, the performance of proposed device is fully better than that of predicate device – the proposed device has longer measurement depth, larger speed range and less error. The acoustic output test has demonstrated that all the probes comply with Track 3 Acoustic Output Limit. Therefore, these items do not impact the safety and effectiveness.

The proposed device, Transcranial Doppler Ultrasound System, is determined to be Substantially Equivalent (SE) to the predicate device, Transcranial Doppler with Robotic Probe Headband, K122710, in respect of safety and effectiveness.