July 8, 2022

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

Re: K213009
Trade/Device Name: Transcranial Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, OQQ
Dated: May 30, 2022
Received: June 8, 2022

Dear Diana 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213009

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.

This device is intended for use by qualified and appropriately trained healthcare professionals. It can be used in hospitals or medical clinics. Mode of Operation is Pulsed Wave (PW) Doppler mode

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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(a)(2).

The assigned 510(k) Number: K213009

1. Date of Preparation: 7/7/2022

2. Sponsor Identification

Shenzhen Delica Medical Equipment Co., Ltd.
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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: +86-21-22815850,
Fax: 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-9M1/EMS-9M2

Regulatory Information
Classification: II
Classification name: Ultrasonic pulsed doppler imaging system
Product Code: IYN;
Regulation Number: 21 CFR 892.1550;
Review Panel: Radiology;

Classification: II
Classification name: Diagnostic ultrasonic transducer
Product Code: ITX, OQQ;
Regulation Number: 21 CFR 892.1570;
Review Panel: Radiology;

Indication 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.

This device is intended for use by qualified and appropriately trained healthcare professionals. It can be used in hospitals or medical clinics. Mode of Operation is Pulsed Wave (PW) Doppler mode.

Device Description:

The EMS-9M1 and EMS-9M2 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.

Both the EMS-9Ml and EMS-9M2 are Track 1 devices.

EMS-9M1 and EMS-9M2 should be used in hospitals or healthcare facilities by doctors or trained healthcare professionals.

5. Identification of Predicate Device

510(k) Number: K173801
Product Name: Transcranial Doppler Ultrasound System

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 60601-2-37:2015, 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: 2014, 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. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device, K173801	Remark
Model	EMS-9M1 / EMS-9M2	EMS-9F	/
Product Code	IYN, ITX and OQQ	IYN, ITX and OQQ	Same
Regulation No.	21 CFR 892.1570	21 CFR 892.1570	Same
Class	II	II	Same
Indication 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	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	Same

	used in fetal applications, and is not intended to be used inside the sterile field. This device is intended for use by qualified and appropriately trained healthcare professionals. It can be used in hospitals or medical clinics. Mode of Operation is Pulsed Wave (PW) Doppler mode.	applications, and is not intended to be used inside the sterile field.	
Configuration	EMS-9M1: Main Unit+ PC/Laptop/Surface+ Transducer EMS-9M2:Main Unit+ PC/Laptop/Surface+ Transducer	Main Unit+ PC/Laptop+ Transducer	Same
Connection modes	EMS-9M1: USB/LAN/WIFI EMS-9M2: USB/LAN/WIFI	USB	Difference

Difference-Connection mode

Compared with the predicate device, the connection mode of EMS-9M1 and EMS-9M2 has additional LAN and WIFI, which makes the proposed device more convenient to use. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Table 2 Specifications Comparison

ITEM		Proposed Device		Predicate Device, K173801	Remark
		EMS-9M1	EMS-9M2	EMS-9F	
Screen		NO	NO	No	Same
Power supply mode		AC Power supply / Internal Power supply	AC Power supply / Internal Power supply	AC power supply	Difference
External Nominal Voltage		AC 100V-240V	AC 100V-240V	DC +12V, -12V, +6V	Difference
Nominal Frequency		50Hz/60Hz	50Hz/60Hz	/	Same
Internal power supply		14.4V 3000mAH	14.4V 3000mAH	/	Difference
Probe		2 MHz PW probe	2 MHz PW probe	2 MHz PW probe	Same
		/	/	4 MHz CW probe	
2MHz PW	Depth	not less 150 mm	not less 150 mm	not less 150 mm	Same
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	10cm/s~300cm/s	Same
	Maximum Error	±15%	±15%	±15%	Same

Difference - Power supply mode

Compared with the predicate device, the proposed devices have one more power supply mode, powered by the built-in battery. The electrical safety testing of proposed device with built-in battery was conducted according to IEC 60601-1, and the test results of electrical safety testing demonstrate that the power supply of built-in battery is acceptable. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Difference - Nominal Voltage

Although the external nominal voltage of proposed device are different with that of predicate device. The electrical safety testing of proposed device was conducted according to IEC 60601-1, and the test results of electrical safety testing demonstrate that the external nominal voltage of proposed device is acceptable. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Difference - Internal power supply

Compared with the predicate device, the predicate device has no internal power supply, and the proposed device has an internal power supply. And the internal power supply provides battery test report and battery specification, this difference will not affect the safety and effectiveness of the proposed device.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device K173801.