Shenzhen Delica Medical Equipment Co., Ltd. June 13, 2019

% Ms. Yolanda Lan
Regulatory Affairs Engineer
6F, Block 10, The Second Industrial Zone, Nanshan District
Shenzhen, Guangdong 51855
CHINA

Re: K190228
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, DXN, DXQ
Dated: March 25, 2019
Received: April 30, 2019

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190228

Device Name
Transcranial Doppler Ultrasound System

Indications for Use *(Describe)*

While the Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system, it can be:
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 robotic probe headband facilitates monitoring use by its ability to track the Doppler signal.

While the Transcranial Doppler Ultrasound System to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The system provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. The noninvasive blood pressure waveform is measured on the subject's finger.
Using the blood pressure calibration module, the system can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The system 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.

The EMS-9D EXP and EMS-9D PRO is intended to be used for subjects above 18 years of age.
The MS-9D EXP and EMS-9D PRO is intended for use in hospitals, clinics and research centers.

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.

Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D EXP/EMS-9D PRO

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							
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 EXP/EMS-9D PRO

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							
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-9DEXP /EMS-9D PRO

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)							

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Diagnostic Ultrasound Indications for Use Format

System: Transcranial Doppler Ultrasound System EMS-9D EXP/EMS-9D PRO

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							
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 EXP/EMS-9D PRO

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 EXP/EMS-9D PRO

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 EXP/EMS-9D PRO

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

Section 6 510(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: K190228

1. Date of Preparation: 03/30/2019

2. Sponsor Identification

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

Establishment Registration Number: 3006441164

Contact Person: Yolanda Lan
Position: Regulatory Affair Engineer
Tel: +86-0755-26413482-115
Fax: +86-0755-86210002
Email: lanxy@delicasz.com

3. Identification of Proposed Device

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

Regulatory Information

Classification: II
Product Code: IYN, ITX and OQQ, DXN, DXQ
Regulation Number: 21 CFR 892.1550 and 21 CFR 892.1570; 21 CFR 870.1130; 21 CFR 870.1120
Review Panel: Radiology;

Indications for Use:
While the Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system, it can be:
1) 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 robotic probe headband facilitates monitoring use by its ability to track the Doppler signal.

While the Transcranial Doppler Ultrasound System to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The system provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. The noninvasive blood pressure waveform is measured on the subject's finger.
Using the blood pressure calibration module, the system can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The system 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.

The EMS-9D EXP and EMS-9D PRO is intended to be used for subjects above 18 years of age.
The EMS-9D EXP and EMS-9D PRO is intended for use in hospitals, clinics and research centers.

Device Description:

EMS-9D PRO and EMS-9D EXP are Transcranial Doppler (TCD) ultrasound system, which is developed based on the EMS-9D, it inherits all the EMS-9D's hardware and mechanical structure design. EMS-9D PRO and EMS-9D EXP are not only a Transcranial Doppler ultrasound system which used non-invasive technique to obtain the information of blood flow velocities throughout the body, but also a blood pressure monitor. This method of measurement is particularly useful for examining the major arteries supplying blood to the brain, and continuously measuring blood pressure.

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.

The EMS-9D PRO and EMS-9D EXP integrate main unit, TCD probes, Nano Core module, upper arm blood pressure module and analog output module (EMS-9D EXP only), dedicated software, remote control, headframe, upper arm cuff, finger cuff and optional probes.

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

4. Identification of Predicate Device

Transcranial Doppler Ultrasound part:

510k Number: K173801

Product Name: Transcranial Doppler Ultrasound System

Manufacturer: Shenzhen Delica Medical Equipment Co., Ltd.

Nano Core Part: (Finger Arterial Blood Pressure)

510k Number: K173916

Product Name: Noninvasive Blood Pressure Monitor

Manufacturer: Finapres Medical Systems B.V.

Upper Arm Cuff Measurement Part:

510k Number: K182433

Product Name: Blood Pressure Cuff

Manufacturer: Shenzhen Caremed Medical Technology Co.,Ltd

5. 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 predicated 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 80601-2-30:2009+A1:2013 Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

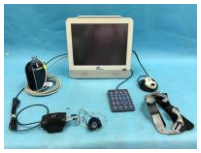
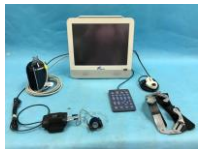
IEC 60601-1-2: 2014, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and teats.

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

6. Substantially Equivalent Discussion

Table 1 Substantially Equivalent Comparison of Transcranial Doppler Ultrasound part

ITEM	Proposed Device	Predicate Device, K173801	Difference?
Product Code	IYN, ITX and OQQ	IYN, ITX and OQQ	no
Regulation No.	21 CFR 892.1550, 21 CFR 892.1570	21 CFR 892.1550, 21 CFR 892.1570	no
Class	II	II	no
Intended Use	Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system: 1) 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. 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.	Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system: 1) 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. 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.	no
Configuration	*EMS-9D EXP: Main Unit + Transducer + NIBP Module* *EMS-9D PRO: Main Unit + Transducer + NIBP Module*	*EMS-9D: Main Unit +Transducer*	*Yes, see analysis 1 below the tables*

ITEM		Proposed Device		Predicate Device, K173801	Difference?
Model		EMS-9D EXP	EMS-9D PRO	EMS-9D	/
Component Family					*Yes, see analysis 1 below the tables*
Screen		15” LCD Display	15” LCD Display	15” LCD Display	no
Nominal Voltage		AC 100V-240V	AC 100V-240V	AC 100V-240V	no
Nominal		50Hz/60Hz	50Hz/60Hz	50Hz/60Hz	no
Input Power		*120VA*	*120VA*	*80VA*	*Yes, see analysis 2 below the tables*
Transducer		1.6/2/16MHz PW probe and 4/8MHz CW probe	1.6/2/16MHz PW probe and 4/8MHz CW probe	1.6/2/16MHz PW probe and 4/8MHz CW probe	no
Performance					
1.6MHz PW	Depth	not less than 150 mm	not less than 150 mm	not less than 150 mm	no
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	10cm/s~300cm/s	no
	Maximum Error	±15%	±15%	±15%	no
2MHz PW	Depth	not less than 150 mm	not less than 150 mm	not less than 150 mm	no
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	10cm/s~300cm/s	no
	Maximum Error	±15%	±15%	±15%	no

ITEM		Proposed Device		Predicate Device, K173801	Difference?
4MHz CW	Depth	not less than 85 mm	not less than 85 mm	not less than 85 mm	no
	Speed range	10cm/s~300cm/s	10cm/s~300cm/s	10cm/s~300cm/s	no
	Maximum Error	±15%	±15%	±15%	no
8MHz CW	Depth	not less than 35 mm	not less than 35 mm	not less than 35 mm	no
	Speed range	10cm/s~200cm/s	10cm/s~200cm/s	10cm/s~200cm/s	no
	Maximum Error	±15%	±15%	±15%	no
16MHz PW	Depth	not less than 8 mm	not less than 8 mm	not less 8 mm	no
	Speed range	10cm/s~120cm/s	10cm/s~120cm/s	10cm/s~120cm/s	no
	Maximum Error	±15%	±15%	±15%	no

Table 2 Substantially Equivalent Comparison of Nano Core

ITEM		***Proposed Device***		***Predicate Device, K173916***	***Difference***
		EMS-9D EXP	***EMS-9D PRO***	***Finapres NOVA Noninvasive Hemodynamic Monitor***	*/*
Nano Core Module	Product Code	*DXQ*	*DXQ*	*DXQ*	*no*
	Regulation No.	*21 CFR 870.1130*	*21 CFR 870.1130*	*21 CFR 870.1130*	*no*
	Classification	*Class II*	*Class II*	*Class II*	*no*

ITEM		Proposed Device		Predicate Device, K173916	Difference
	Intended Use	To be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The system provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. The noninvasive blood pressure waveform is measured on the subject's finger.	To be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The system provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. The noninvasive blood pressure waveform is measured on the subject's finger.	The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals.	*no*
	Intended Patient	Adult	Adult	Adult	no
	Blood pressure measurement range	*0~300mmHg*	*0~300mmHg*	*0-330 mmHg*	*Yes, see analysis 3 below the tables*
	Measurement accuracy	±3mmHg	±3mmHg	max. ± 3 mmHg	no
	PR Measurement Range	0-214 bpm	0-214 bpm	0-214 bpm	no
	PR Measurement accuracy	*±1bpm*	*±1bpm*	*± 5 bpm average*	*Yes, see analysis 3 below the tables*
	Finger Cuff Size	Large, medium, small	Large, medium, small	Large, medium, small	no
Note: The submitter simply buying the Nano Core Module from Finapres, please refer to *042_18.5 Finapres-Delica Purchase Agreement & 043_18.6 Statement of HK Affiliate & Upper Arm Cuff*					

Table 3 Substantially Equivalent Comparison of Upper Arm Cuff Measurement part

ITEM		***Proposed Device***		***Predicate Device, K182433***	***Difference?***
		EMS-9D EXP (Upper Arm Cuff Model: N1A-PS)	***EMS-9D PRO (Upper Arm Cuff Model: N1A-PS)***	***Caremed Reusable Blood Pressure Cuff***	***/***
Upper Arm measurement cuff module	Regulation No.	21CRF 870.1120	21CRF 870.1120	21CRF 870.1120	no
	Classification	Class II	Class II	Class II	no
	Product Code	DXQ	DXQ	DXQ	no
	Intended use	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused.	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused	no
	Patient Populations	Adult	Adult	Adult	no
	Circumference	25-35cm	25-35cm	25-35cm	
	Pressure Range	0-300 mmHg	0-300 mmHg	0-300 mmHg	no
	Sterility	Non-sterile	Non-sterile	Non-sterile	no
	Max. Leakage	< 4mm Hg/ min.	< 4mm Hg/ min.	< 4mm Hg/ min.	no
	Material	Cuff (Patient contacted): PU	Cuff (Patient contacted): PU	Cuff (Patient contacted): PU	no

ITEM		Proposed Device		Predicate Device, K182433	Difference?
	Biocompatibility	Comply with ISO 10993-5; Comply with ISO 10993-10	Comply with ISO 10993-5; Comply with ISO 10993-10	Comply with ISO 10993-5; Comply with ISO 10993-10	no
Note: The submitter simply buying the cuff from Caremed, K182433, please refer to *043_18.6 Statement of HK Affiliate & Upper Arm Cuff*					

SE Analysis 1 – Configuration and Component Family

Compared with the predicate device, the Non-Invasive Blood Pressure (NIBP) module was added thus there are added accessories of NIBP. The NIBP module consists of Nano core module and upper arm cuff measurement module. NIBP module added use an internal USB transform, though these changes do constitute a change in the fundamental scientific technology of the device, the IEC 60601-1 test was performed and turns out positive results. Therefore, these items do not impact the safety and effectiveness.

SE Analysis 2 – Input Power

Although the input power of proposed device is much higher than that of predicate device, both proposed device and predicate device comply with IEC 60601-1, IEC 60601-2 and IEC 60601-2-37, and the proposed device also comply with ISO 80601-2-30, the test report can demonstrate the electrical safety and EMC of proposed device. Therefore, these items do not impact the safety and effectiveness.

SE Analysis 3 – Performance (Blood Pressure Measurement Range & PR Measurement accuracy)

Referring to the comparing table, the performance of Ultrasound Doppler Part of proposed device is identical to that of predicate device, the performance of NIBP part is better than that of predicate device. And the particular performance test has demonstrated that the NIBP module complies with the particular requirements for the safety and essential performance of automated non-invasive sphygmomanometers. Therefore, these items do not impact the safety and effectiveness. And the rationale for not perform IEC 60601-2-37 and NEMA UD2 test refer to 019 *Section 16 Rationale for NEMA UD-2 testing not needed.*