September 6, 2019

Huntleigh Healthcare Ltd
Steve Monks
Quality Manager
35 Portmanmoor Road
Cardiff, CF24 5HN
United Kingdom

Re: K183574
Trade/Device Name: DMX/SRX Handheld Doppler and Probes
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW, DXQ, JOM, JAF, HGL, KNG
Dated: August 14, 2019
Received: August 19, 2019

Dear Steve Monks:

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,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183574

Device Name
DMX / SRX Handheld Doppler and Probes

Indications for Use *(Describe)*
The DMX Handheld Doppler:

Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the non-invasive assessment of vascular blood flow to assist in diagnosis.

The SRX Handheld Doppler:

Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the assessment of fetal heart rate to assist in diagnosis.

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.

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HUNTLEIGH

510(k) Summary
DMX / SRX Handheld Doppler and Probes

Name & Address:	Huntleigh Healthcare Limited - Diagnostic Products Division Unit 35, Portmanmoor Road Cardiff CF24 5HN United Kingdom
Telephone:	+44 (0)2920 485885
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Prepared:	July 2019
Contact:	Steve Monks

Device Name:	DMX / SRX Handheld Doppler and Probes
Common Name (DMX / Vascular Use)	Cardiovascular Blood Flowmeter / Non-Fetal Ultrasonic Monitor / Hydraulic, pneumatic, photoelectric plethysmographs / Transducer, ultrasonic, obstetric / Blood pressure cuff

Classification (DMX / Vascular Use)

Class	Product Code	Classification Regulation
II	DPW	870.2100
II	JAF	892.1540
II	JOM	870.2780
II	HGL	884.2960
II	DXQ	870.1120

Classification Name: (DMX / Vascular Use)	Flowmeter, Blood, Cardiovascular
Predicate Devices: (DMX / Vascular Use)	MD2 family of Handheld vascular and obstetric Dopplers and probes (HS range) manufactured by Huntleigh Healthcare (K930200) Vascular Assist manufactured by Huntleigh Healthcare (K002186)
Indications for Use: (DMX / Vascular Use)	Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the non-invasive assessment of vascular blood flow to assist in diagnosis.
Description : (DMX / Vascular Use)	The DMX Doppler provides the clinician with the ability to perform vascular investigations. It is powered from two internal replaceable AA format 1.5 volt alkaline or 1.2 volt NiMH rechargeable batteries. The DMX hand unit is used with a Doppler or Arterial Photoplethysmography (APPG) probe, selected to suit the nature of the investigation to be performed. The device includes a colour liquid crystal display and three soft keys for user input. Doppler audio sounds are reproduced by the integral loudspeaker; the audio level can be adjusted by two buttons. **Doppler Mode:** The probes emit low energy ultrasonic waves into the body which are reflected back into the probe. The reflected ultrasonic waves contain information about the blood flow, which can be heard as audio sounds from the loudspeaker and waveforms presented on the display. There is a range of compatible Doppler probes; the choice of probe is determined by the type of vascular assessment being performed and depth of vessel.

APPG Mode:

The APPG sensor emits low energy infra-red light into the body, some of which is reflected by blood within the tissue back into the sensor. The variation of this reflected light is related to the blood volume within the tissue. The APPG probe is used with an inflatable cuff and sphygmomanometer gauge to measure toe / finger blood pressures.

Dopplex Reporter 5 (DR5) Software Package:

The DR5 software is a medical device data system (MDDS) and is an optional accessory to the dopplex® DMX bidirectional Doppler. It can display bidirectional velocity/time waveforms obtained from various vessels. Data can be archived and a printout can be obtained for patients notes. The DR5 is not a standalone medical device – it can only be used with the DMX Doppler to display, archive and print Doppler waveforms and PPG pressures produced by the DMX.

Note: Being an MDDS, the device is exempt from premarket notification and a letter to file against K930200/S2 will be completed, detailing the update in software version, of the already registered Dopplex Reporter Software package.

Models:
(DMX / Vascular Use)

There are two vascular versions:

DMX (non-rechargeable version)

DMXR (rechargeable version)

The DMXR is contained in two different Vascular assessment kits:

DMXRABI – Ankle Brachial Index Kit

DMXRATP – Ankle and Toe Pressure kit

The vascular probes include:

VP4XS – 4MHz Vascular Doppler Probe

VP5XS – 5MHz Vascular Doppler Probe

VP8XS – 8MHz Vascular Doppler Probe

EZ8XS – 8MHz Widebeam Vascular Doppler Probe

VP10XS – 10MHz Vascular Doppler Probe

PPGA1 – Photoplethysmography Probe

Common Name (SRX /Obstetric Use)

Fetal ultrasonic Monitor and accessories / Obstetric Ultrasonic Transducer

Classification (SRX /Obstetric Use)

Class	Product Code	Classification Regulation
II	KNG	884.2660
II	HGL	884.2960

Classification Name: (SRX /Obstetric Use)	Fetal ultrasonic Monitor and accessories
Predicate Devices: (SRX /Obstetric Use)	MD2 family of Handheld vascular and obstetric Dopplers and probes (HS range) manufactured by Huntleigh Healthcare (K930200)
Indications for Use: (SRX /Obstetric Use)	Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the assessment of fetal heart rate to assist in diagnosis.
Description : (SRX /Obstetric Use)	The SRX Doppler range is intended to be used by qualified healthcare practitioners for the detection and presentation of the fetal heart rate to assist in the assessment of fetal well-being during pregnancy. Each model is powered from two internal replaceable AA format 1.5 volt alkaline or 1.2 volt NiMH rechargeable batteries. The SRX hand unit is used with a choice of either a 2MHz (OP2XS) or 3MHz (OP3XS) obstetric Doppler probe. The SR2 and SR3 have fixed probes (2MHz and 3MHz respectively). All models include a colour liquid crystal display and three soft keys for user input. Doppler audio sounds are reproduced by the integral loudspeaker; the audio level can be adjusted by two buttons. The probes emit low energy ultrasonic waves into the body some of which are reflected back into the probe. The reflected ultrasonic waves contain information about the fetal heart, which can be heard as audio sounds from the loudspeaker and heart rate values presented on the display.
Models: (SRX /Obstetric Use)	There are six obstetric versions: SRX (non-rechargeable version) interchangeable probe capable SRXR (rechargeable version) interchangeable probe capable SR2 fixed 2MHz probe (non-rechargeable) SR2R fixed 2MHz probe (rechargeable) SR3 fixed 3MHz probe (non-rechargeable) SR3R fixed 3MHz probe (rechargeable) The obstetric probes include: OP2XS – 2MHz Obstetric Doppler Probe OP3XS – 3MHz Obstetric Doppler Probe
Comparison of Technological	Doppler Ultrasound and Infrared Photoplethysmography (PPG) are the technological principles for both the subject and

Characteristics with Predicate Devices (DMX – Vascular Use)	predicate devices. It is based on the combination of a handheld 'monitor' and a cable attached Doppler probe or PPG probe, changing the probe changes the functionality of the monitor to the corresponding mode.

DOPPLER MODE (*selected automatically by fitting a Doppler probe*):

The subject and the predicate (Huntleigh MD2) are based on the following same technological elements:

- The monitor provides the power to the probe
- The monitor and probes have a probe identification (ID) system
- The monitor provides a Doppler signal audio output via internal loudspeaker or optional headphones
- The monitor performs filtering of the Doppler signal
- The monitors have LCD displays
- The monitor displays the Probe frequency
- The monitors are available either with rechargeable or primary batteries
- The monitor provides a graphical battery power level indication
- The Doppler probes are functionally identical

The following technological differences exist between the subject device and predicate (Huntleigh MD2) device:

- The subject device displays the 'Maximum Frequency' flowrate waveform for forward and reverse blood flow; the predicate displays flowrate as a bar graph (4 levels in each direction)
- The subject device can store multiple blood flow waveforms that can be recalled and played back; the predicate does not have this capability.
- The subject device has a 320 x 240 Pixel Colour Graphic LCD, whereas the predicate has a fixed character monochrome LCD.
- The subject has a USB interface whereas the predicate has an RS232 interface
- The user controls of the subject device are 'soft keys', the function of which is identified by the LCD whereas the predicate has 'fixed' function buttons
- Audio volume of the subject device is controlled by an up and a down button, whereas the predicate uses a rotary volume control

APPG MODE (*selected automatically by fitting an APPG probe*):

The subject device and the predicate (Huntleigh Vascular Assist) are based on the same following technological elements:

- The device can store multiple APPG waveforms and pressures that can be recalled, displayed and 'replayed'.
- The monitor provides the power to the probe
- The monitor and probe have a probe identification (ID) system
- The subject and predicate have colour LCD displays

The following technological differences exist between the subject device and predicate (Huntleigh Vascular Assist) device:

- The subject LCD is smaller than the predicate
- The subject can operate on either rechargeable battery or primary battery; the predicate can only operate on rechargeable battery.
- The subject has a USB interface whereas the predicate has an RS232 interface

Comparison of Technological Characteristics with Predicate Devices (SRX – Obstetric Use)

Doppler Ultrasound is the technological principle for both the subject and predicate devices. It is based on the combination of a handheld 'monitor' and a cable attached Doppler probe.

The subject and the predicate (Huntleigh MD2) are based on the following same technological elements:

- The monitor provides the power to the probe
- The monitor and probes have a probe identification (ID) system
- The monitor provides a Doppler signal audio output via internal loudspeaker or optional headphones
- The monitor performs filtering of the Doppler signal
- The monitors have LCD displays
- The monitor displays the Probe frequency
- The monitors are available either with rechargeable or primary batteries
- The monitor provides a graphical battery power level indication
- The Doppler probes are functionally identical

The following technological differences exist between the

subject device and predicate (Huntleigh MD2) device:

- The subject device can display fetal heart rate in numerical format and graphically, whereas the predicate can only display fetal heartrate numerically.
- The subject device can store multiple fetal heartrate traces that can be recalled, displayed and replayed, which the predicate cannot.
- The subject device has a 320 x 240 Pixel Colour Graphic LCD, whereas the predicate has a fixed character monochrome LCD.
- The subject device has a USB interface, whereas the predicate has an RS232 interface
- The user controls of the subject device are 'soft keys', the function of which is identified by the LCD, whereas the predicate has 'fixed' function buttons
- Audio volume of the subject device is controlled by an up and a down button, whereas the predicate uses a rotary volume control

Substantial Equivalence:

The DMX / SRX Handheld Dopplers and Probes are substantially equivalent to the cleared devices Huntleigh MD2 and probes (K930200) and Huntleigh Vascular Assist (K002186)

Performance Data:

Testing to demonstrate substantial equivalence included:

Testing Conducted	Discussion
Biocompatibility Testing -Cytotoxicity -Sensitization -Irritation	The biocompatibility evaluation of the device was conducted in accordance with *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.* The subject device is considered a skin contacting device (intact) for a duration of <24 hours.
Software Performance Testing	Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content for the Premarket Submissions for

	Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern as a malfunction or a latent design flaw in the software device could lead to an erroneous diagnosis or a delay in the delivery of appropriate medical care, that would likely lead to minor injury.
Electronic Hardware Performance Testing	Testing provides verification of electronic hardware performance including power, user interface, display, audio, data management and time and date.
Mechanical Performance Testing	Testing provides verification of mechanical performance including general, enclosure, physical, environment, labelling, IFU, packaging, durability and life testing.
Electrical Safety Testing	Electrical safety testing was conducted on the product by a third party laboratory, UL. Testing confirms device complies with IEC 60601-1:2005 (Third Edition) + A1:2012, IEC 60601-1-11, IEC 60601-1-6 and IEC 60601-2-37.
EMC Testing	EMC testing was conducted on the product by a third party laboratory, UL. Testing confirms device complies with IEC 60601-1-2:2014
Environmental Performance Testing	Testing provides verification of the operating and storage temperature, humidity and atmospheric pressure.

Technologies Summary:

The DMX / SRX hand held Dopplers and Probes consist of an internally powered 'monitor' with either primary cells or rechargeable (determined as a purchase option), these are used to create the various internal voltages required to drive the colour 240 x 320 pixel TFT LCD, the microprocessor, analogue electronics, audio amplifier and probe.

All versions of the DMX/SRX provide audio representation of the Doppler signal via and audio amplifier and internal speaker, with the ability to connect headphones via a 3.5mm jack socket.

The range of DMX / SRX compatible Huntleigh Doppler probes contain all the transmit (piezo transducer excitation) and receive electronics; the output from the probes are two analogue signals in phase quadrature which are fed into the DMX / SRX for processing.

The APPG probe includes an optical sensor which contains an infra red light emitting diode (LED) and photo transistor. The LED output is modulated at 1 kHz. The phototransistor output feeds into an amplifier that is synchronous with the LED drive signal, which helps to reduce the effect of ambient light. The amplified signal is bandpass filtered before being fed to the monitor unit. This signal represents relative blood volume changes, and is not calibrated.

Located inside the APPG module is an air pressure measurement sensor which records the instantaneous cuff pressure. The cuff pressure values are presented on the DMX display allowing the user to determine the actual systolic blood pressure.

All versions of the DMX / SRX range have the same internal hardware; the determination whether it is a 'Vascular' DMX or one of the 'Obstetric' SRX, SR2* or SR3* models is determined by a single 'link' on the main PCB, and external labels.

The SR2 and SR3 models are also determined by having fixed 'Obstetric' Doppler probes.

The probes used with DMX and SRX models can be easily interchanged by the user.

The DMX version is a 'Vascular' investigation device. Connecting one of a range of vascular Doppler probes sets the DMX to vascular Doppler mode and connecting the APPG probe sets the DMX to Photoplethysmography mode. It is possible to connect an Obstetric Doppler probe to the DMX which will provide full obstetric functionality.

The SRX version is an 'Obstetric' investigation device. Connecting either of the available Obstetric Doppler probes sets the SRX to Obstetric mode. It is possible to connect a vascular Doppler probe which will provide an audio only

	Doppler output. It is physically possible to connect an APPG probe to the SRX, but the SRX will not recognise the probe and therefore has no effect.
Conclusion:	The data detailed within this submission demonstrates that the device is as safe and effective and performs as well as the predicate devices identified in this summary, which are currently marketed for the same intended use. The device hardware, software, mechanical and clinical performance verification demonstrates that it should perform as intended in the specified user conditions.