November 27, 2019

Directed Systems Ltd
Mark Leaning
Chief Executive Officer
St John's Innovation Centre, Cowley Road
Cambridge, CB4 0WS Gb

Re: K190955
Trade/Device Name: Hypotension Decision Assist
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: May 10, 2019
Received: May 17, 2019

Dear Mark Leaning:

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)*

K190955

Device Name

Hypotension Decision Assist

Indications for Use *(Describe)*

Hypotension Decision Assist is indicated to acquire, process and display arterial pressure and other key cardiovascular characteristics of adult patients who are at least eighteen years of age that are undergoing surgery where their arterial pressure is being continuously monitored by a vital-signs monitor. It is indicated for use to assist anesthesia healthcare professionals manage the blood pressure, hemodynamic stability and the cardiovascular system during such surgery.

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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510(k) Summary (K190955)

This 510(k) summary for Hypotension Decision Assist is supplied as required by 21 CFR 807.92(c)

Applicant:

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Preparation Date:

09 April 2019

Trade / Proprietary Name:

Hypotension Decision Assist

Common Name:

Clinical decision support software

Classification Name:

Single-function, preprogrammed diagnostic computer

Regulation:

21 CFR 870.1435

Product Code:

DXG

Predicate Device:

Navigator™ (K092219) from Applied Physiology Pty Ltd

Reference Devices:

CardioQ-EDM+ (K172457) from Deltex Medical Ltd

IntelliVue Patient Monitor MX550 (K161531) from Philips Medizin Systeme Boeblingen GmbH

CARESCAPE Monitor B450 (K132533) from GE Healthcare

Device Description:

Hypotension Decision Assist (HDA) is a clinical decision support Software as a Medical Device (SaMD) that is installed upon a medically-rated touch-screen computer. HDA connects to a multi-parameter patient monitor supplied by other manufacturers, from which it acquires vital signs data continuously including the arterial blood pressure waveform and cardiovascular-related numeric parameters.

HDA continually processes this data to display, in graphical charts and numeric format, vital signs data and derived variables including mean arterial pressure (MAP), heart rate, systolic and diastolic blood pressure, cardiac output and systemic vascular resistance. HDA compares MAP to user set targets to indicate when MAP is above or below the target range. It allows the user to mark the administration of vasopressors and volume challenges to the MAP trend.

Intended Use:

HDA is a clinical decision support medical device intended to assist healthcare professionals in managing blood pressure and the cardiovascular system in patients undergoing anesthesia during surgical procedures.

Indications for Use:

HDA is indicated to acquire, process and display arterial pressure and other key cardiovascular characteristics of adult patients who are at least eighteen years of age that are undergoing surgery where their arterial pressure is being continuously monitored by a vital-signs monitor. It is indicated for use to assist anesthesia healthcare professionals manage the blood pressure, hemodynamic stability and the cardiovascular system during such surgery.

Comparison of Technological Characteristics with the Predicate Device:

HDA has the same intended use as the Navigator predicate. They are both intended to assist physicians to manage the blood pressure and cardiovascular stability of patients undergoing anesthesia during surgery.

The subject and predicate device have the following same technological characteristics:

- Clinical decision support software
- Supplied on a medical grade touch screen computer
- Used with patients whose arterial pressure is being continuously monitored by a vital signs monitor.
- Input data received from a vital signs monitor
- Input data received using same communications protocols (HDA supports a subset of Navigator's supported communications protocols)
- Provides clinicians with a graphical display of monitoring and support information as a visual aid in determining a patient's cardiovascular state.
- Displays information on mean arterial pressure (MAP), cardiac output and systemic vascular resistance

The following differences in technological characteristics exist between the subject and predicate device:

- The predicate device acquires MAP and cardiac output from the arterial waveform signal provided by the vital signs monitor whereas the subject device derives these parameters from the arterial waveform input. The CardioQ-EDM+ (K172457), IntelliVue Patient Monitor MX550 (K161531) and CARESCAPE Monitor B450 (K132533) from GE Healthcare are provided as reference devices for the derivation of physiological parameters from input arterial waveform input.
- The subject device displays systolic blood pressure, diastolic blood pressure and heart rate values that are not displayed by the predicate device. These values are derived from the input arterial waveform signal as is the case with the IntelliVue Patient Monitor MX550 (K161531) reference device.
- The predicate device acquires Right Arterial Pressure (RAP) and oxygen saturation data from the vital signs monitor which are not relevant to HDA.

Performance Data

System verification testing:

The initial system verification was performed to confirm the interactivity of the system interface and to confirm that HDA could process and display the physiologic parameters required for its intended use.

Measurement accuracy verification:

The measurement accuracy of HDA across the intended use measuring range for each of its measured physiologic parameters was verified by bench testing following the approach of the IEC 60601-2-34 Edition 3.0 2011-05 standard that is recognized by FDA. This testing also demonstrated the substantial equivalence of this measurement accuracy to that of the reference devices and verified that the performance of HDA is equivalent when connected to the both of the vital signs monitors types that it is specified for use with.

Artefact Detection Verification

Bench testing was performed to confirm that HDA is capable of detecting each of the signal artefacts and anomalies that have the potential to impact its performance.

Predicate comparison testing

Bench testing was performed to compare the performance of HDA to that of its predicate device with respect to the detection of cardiac output and systemic vascular resistance events.

Power Interruption testing

Bench testing was performed in accordance with the IEC 60601-2-34 Edition 3.0 2011-05 standard that is recognized by FDA to verify that HDA can tolerate a sudden power interruption without loss of either user-input data, or patient data while remaining in the correct operating mode.

Summative Usability Testing

Summative usability testing was performed following the FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff” to demonstrate that HDA fulfils the needs of its intended users.

Software Verification and Validation Testing

Software verification and validation testing was performed and documentation was provided in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" requirements for a moderate level of concern device. HDA is considered a moderate level of concern device because a malfunction of, or a latent design flaw in the device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted on the touch screen computer on which HDA is installed. The computer complies with the FDA recognized standards ES60601-12005/(R)2012 and A1:2012 for safety and IEC60601-1-2:2014 for EMC.

Clinical studies

Clinical studies were not performed. However, patient data sets obtained from internationally recognized databases were used in the original system verification and the bench testing performed to compare the performance of HDA to the predicate device. These patient data sets were selected because they are representative of the range of data input and signal quality that will be encountered in the intended use population and environment of use of the device.

Conclusion:

The non-clinical bench testing and hardware and software verification support the safety of HDA and verify that it can accurately measure the physiologic parameters associated with its intended use. Bench testing has demonstrated that the accuracy of its measurements is substantially equivalent to its predicate or reference devices. Direct comparison testing of HDA to its predicate has demonstrated that it performs comparably to its predicate device.