November 23, 2021

Directed Systems Ltd
Mark Leaning
Chief Executive Officer
47-51 Norfolk Street
Cambridge, Cambridgeshire CB1 2LD
United Kingdom

Re: K212529
Trade/Device Name: Hypotension Decision Assist Model HDA-OR2
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, preprogrammed diagnostic computer
Regulatory Class: Class II
Product Code: DXG
Dated: October 27, 2021
Received: October 29, 2021

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,

for

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212529

Device Name
Hypotension Decision Assist HDA-OR2

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

This 510(k) summary for Hypotension Decision Assist HDA-OR2 is supplied as required by 21 CFR 807.92(c)

Applicant:

Directed Systems Ltd

47-51 Norfolk Street,

Cambridge

Cambridgeshire CB1 2LD

United Kingdom

Telephone: 011 44 7552 747389

Contact:

Mark S. Leaning

Chief Executive Officer

Telephone: 011 44 7552 747389

Email: markleaning@directedsystems.com

Preparation Date:

27 October 2021

Trade / Proprietary Name:

Hypotension Decision Assist

Model #:

HDA-OR2

Common Name:

Clinical decision support software

Classification Name:

Single-function, preprogrammed diagnostic computer

Regulation:

21 CFR 870.1435

Product Code:

DXG

Predicate Device:

Hypotension Decision Assist HDA-OR1 (K190955)

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-OR2 has the same intended use and indications for use as the HDA-OR1 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
- Allows serial connection to vital signs monitor
- Input data received using same communications protocols
- Acquires arterial waveform signal provided by the vital signs monitor

- Derives and displays from the input arterial waveform signal; systolic blood pressure, diastolic blood pressure, MAP, heart rate, and short term changes in heart rate, cardiac output and systemic vascular resistance
- Provides clinicians with a graphical display of monitoring and support information as a visual aid in determining a patient's cardiovascular state.
- Allows marking of the administration of bolus or infused vasopressors and volume challenges

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

- HDA-OR2 is supplied with a tablet computer with an internal battery whereas the predicate HDA-OR1 is supplied with a mains powered all-in-one computer without a battery.
- HDA-OR2 allows connection to Philips patient monitors via a wireless or wired network connection. The predicate HDA-OR1 only allows connections via a serial connection.
- HDA-OR2 allows uploading of its log data to secure cloud storage over the internet. The predicate HDA-OR1 is not internet enabled and only allows log data to be downloaded to connected USB drives.
- HDA-OR2 can download software updates from a secure API over the internet. The predicate HDA-OR1 is not internet enabled and can only download software updates from connected USB drives.

Performance Data

System verification testing:

The subject device was subjected to the system regression testing for HDA. This system regression testing consolidates the performance testing that was presented in the submission for the predicate HDA-OR1 and included:

Measurement accuracy verification:

The measurement accuracy of HDA across the intended use measuring range for each of its measured physiologic parameters 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 demonstrated the measurement accuracy over the serial and network connections available for the subject device.

Artefact Detection Verification

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

Power Interruption testing

Bench testing 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 including when the battery is disconnected.

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 supplied with HDA-OR2. The computer complies with the FDA recognized standards ES60601-1 2005/(R) 2012 and A1:2012 for safety and IEC60601-1-2:2014 for EMC.

Remote update of software in an electromagnetically noisy environment testing

Testing was performed of HDA's ability to receive remote updates in an electromagnetically noisy environment such as would be found in a hospital installation site. This testing confirmed that HDA can receive remote updates in such an electromagnetically noisy environment, that it will respond as designed and not install updates that are interrupted (interfered or dropped) during wireless communication and that it can detect and reject malware masquerading as legitimate updates.

Conclusion:

The bench testing and hardware and software verification support the safety of HDA-OR2 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 device and that HDA-OR2 performs as well as its predicate device.