December 17, 2019

Edwards Lifesciences, LLC
Jamie Byun
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K193179
Trade/Device Name: EV1000 Clinical Platform
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DXG
Dated: November 15, 2019
Received: November 18, 2019

Dear Jamie Byun:

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)*
K193179

Device Name
EV1000 Clinical Platform

Indications for Use *(Describe)*
The EV1000 Clinical Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous or intermittent assessment. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. Analysis of the thermodilution curve in terms of mean transit time and the shape is used to determine intravascular and extravascular fluid volumes. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The EV1000 Clinical Platform may be used in all settings in which critical care is provided.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or nonsurgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Hypotension Prediction Index (HPI) parameter.

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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SECTION 5 - 510(K) SUMMARY

EV1000™ Clinical Platform(s) Special 510(k) Corrective Action Being Effected	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Jamie Byun
Date Prepared	November 15, 2019
Trade Name	EV1000 Clinical Platform™
Common Name	Cardiac Output / Oximetry Monitor
Classification Name	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Regulation Class / Product Code	Class II DXG
Primary Predicate Device(s)	K160552 – EV1000 Clinical Platform™ (cleared 06/01/2016)
Reference Device(s)	K192058 – EV1000 Clinical Platforms: Special 510(k) Corrective Action Being Effected
Device Description	**EV1000 Clinical Platform (EV1000A)** The EV1000 Clinical Platform measures patient physiologic parameters in a minimally invasive manner when it is used as a system with various Edwards' components, including the Edwards pressure transducers, the FloTrac sensor, the components of the VolumeView System, oximetry catheters/sensors, and the corresponding accessories applied to the patient. The EV1000 Clinical Platform includes an Acumen Hypotension Prediction Index (HPI) feature, which is an index related to the likelihood of a patient experiencing a hypotensive event (defined as mean arterial pressure (MAP) < 65 mmHg for one minute in duration) within 15 minutes, where zero (0) indicates low likelihood and one hundred (100) indicates high likelihood. The Acumen Hypotension Prediction Index, HPI, should not be used exclusively to treat patients. A review of the patient's hemodynamics is recommended prior to initiating treatment. The EV1000 Clinical Platform consists of the EV1000 Monitor (Monitor), the EV1000 Databox (Databox), and an Ethernet cable to connect the Databox to the Monitor. It may be attached to the patient bedside, an IV pole or roll stand. A design hardware change for the AC inlet related to a corrective action was made. The additional hardware for the EV1000A power adaptor consists of a Power Adapter Cover (ingress protector) that is used to

	prevent liquid ingress or other conductive contaminates from entering the AC inlet.
Indications for Use/Intended Use	The EV1000 Clinical Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous or intermittent assessment. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. Analysis of the thermodilution curve in terms of mean transit time and the shape is used to determine intravascular and extravascular fluid volumes. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The EV1000 Clinical Platform may be used in all settings in which critical care is provided. The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or nonsurgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Hypotension Prediction Index (HPI) parameter.
Comparative Analysis	EV1000 Clinical Platform (EV1000A) has been modified by adding a Power Adapter Enclosure to the power adaptor in order to prevent liquid ingress. Design verification testing for the EV1000A power adaptor with the Power Adapter Enclosure was performed and a reduction in occurrences of liquid ingress at the AC inlet was achieved.
Functional/ Safety Testing	The EV1000 Clinical Platform (EV1000A) has successfully passed functional and bench studies to demonstrate that the device is substantially equivalent to the cited predicate device and the Power Adapter Cover reduces the possibility of fluid ingress.
Conclusion	The EV1000 Clinical Platform (EV1000A) has been shown to be safe and is substantially equivalent to the predicate device for its intended use in hospitals and other appropriate clinical environments.