January 22, 2021

Edwards Lifesciences, LLC
Christine Chun
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K203131
Trade/Device Name: EV1000 Clinical Platform Non-Invasive (NI) or ClearSight System, EV1000 Clinical Platform
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, DXG, QAQ
Dated: December 22, 2020
Received: December 23, 2020

Dear Christine Chun:

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 LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K203131

Device Name
EV1000 Clinical Platform (EV1000A)

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. Monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol enables consistent fluid management in the intended patient populations. 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 non-surgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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)*
K203131

Device Name
EV1000 Clinical Platform NI (EV1000NI)

Indications for Use *(Describe)*
The EV1000 Clinical Platform NI and the ClearSight finger cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. In addition, the noninvasive system is indicated for use in patients with comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform NI and the ClearSight finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

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)

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SECTION 5 – 510(k) SUMMARY

EV1000™ Clinical Platform(s) 510(k)		
Submitter – 807.92(a)(1)		
510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	Christine J. Chun, MBA One Edwards Way Irvine, CA 92614 christine_chun@edwards.com (949) 250-2773	
Date Prepared	October 16, 2020	
Device Information – 807.92(a)(2)		
Trade Name	EV1000 Clinical Platforms	
	EV1000 Clinical Platform™ NI **(EV1000NI)**	EV1000 Clinical Platform **(EV1000A)**
Common Name	Non-Invasive Blood Pressure Measurement System	Cardiac Output / Oximetry Monitor with Adjunctive Predictive Cardiovascular Indicator
Classification Name	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) System, Measurement, Blood-Pressure, Non-Invasive (21 CFR 870.1130)	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) Adjunctive Predictive Cardiovascular Indicator (21 CFR 870.2210)
Regulation Class / Product Code	Class II DXG, DXN	Class II DXG, QAQ
Predicate Device – 807.92(a)(3)		
Legally Marketed Devices	EV1000 Clinical Platforms	
	EV1000 Clinical Platform™ NI **(EV1000NI)**	EV1000 Clinical Platform **(EV1000A)**
Primary Predicate Device(s)	K160552 – EV1000 Clinical Platform™ NI with ClearSight™ Finger Cuffs or ClearSight™ System (cleared 06/01/2016)	K160552 – EV1000 Clinical Platform (cleared 06/01/2016)
Additional Predicate Device(s)	K201446 - HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (cleared 10/01/2020 K190205 - HemoSphere Advanced Monitor, HemoSphere Tissue Oximetry Module (cleared 08/29/2019) K180881 - HemoSphere Advanced Monitor, HemoSphere Pressure Cable (cleared 11/16/2018)	K183646 - Acumen™ Hypotension Prediction Index (HPI) – EV1000 Clinical Platform (cleared 05/21/2019) K190205 - HemoSphere Advanced Monitor, HemoSphere Tissue Oximetry Module (cleared 08/29/2019) K180881 - HemoSphere Advanced Monitor, HemoSphere Pressure Cable (cleared 11/16/2018)

Device Description – 807.92(a)(4)

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.

No changes were made directly to the EV1000A system (i.e. Databox). However, since the monitor (EV1000M) is shared by the both platforms (EV1000A and EV1000NI), the new software updates, Fluid Responsiveness Test feature, enhanced cybersecurity, and data download option to the EV1000NI impacted the EV1000A platform. Additionally, dP/dt, Eadyn, and PPV as key parameters, as well as minor updates to the graphic user interface to the key parameters and secondary screens were reflected in the operator's manual. All of these software changes reside in the EV1000 monitor.

EV1000NI:

The EV1000 Clinical Platform NI with ClearSight finger cuffs is a non-invasive monitor that enables the continuous assessment of a patient's hemodynamic function based on the scientific method of Peňàz – Wesseling. The device measures continuous non-invasive blood pressure (Systolic, Diastolic, and Mean Arterial Pressure) and pulse rate. Cardiac Output and other hemodynamic parameters are derived from the blood pressure waveform.

The EV1000 NI consists of the EV1000 monitor (EV1000M), the EV1000 Pump-Unit (Pump-Unit), a Pressure Controller (PC2K or PC2) that is worn on the wrist, a Heart Reference Sensor (HRS), and Edwards ClearSight finger cuffs (It may be attached to the patient bedside, an IV pole or roll stand.

Software modifications were made to support new features such as Fluid Response Interpretation, Blood Pressure Calibration, ClearSight Workflow Options, Focused Screens, enhanced error messaging/help screens, finger cuff brand recognition, enhanced cybersecurity updates, data download options, and Heart Reference Sensor (HRS) EEPROM update were included as part of this submission.

Indications for Use/Intended Use – 807.92(a)(5)

EV1000 Clinical Platform (EV1000A):

No changes are being made to the indications for use as part of the 510(k) for EV1000A

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. Monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol enables consistent fluid management in the intended patient populations. 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 non-surgical 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.

EV1000 Clinical Platform™ NI (EV1000NI):

No changes are being made to the indications for use as part of the 510(k) for EV1000NI

The EV1000 Clinical Platform NI and the ClearSight finger cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. In addition, the noninvasive system is indicated for use in patients with comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform NI and the ClearSight finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

Comparative Analysis – 807.92(a)(6)

Technical Characteristics (Similarity)	EV1000 Clinical Platforms	
	EV1000 Clinical Platform™ NI (EV1000NI)	**EV1000 Clinical Platform (EV1000A)**
	Non-Invasive ClearSight technology: The technological characteristics of the predicate and subject devices are identical.	**Minimally Invasive Technology:** The technological characteristics of the predicate and subject devices are identical.

The purpose of this Traditional 510(k) submission is to obtain clearance of EV1000™ Clinical Platform (EV1000A) and EV1000™ Clinical Platform NI (EV100NI) with software modifications to incorporate the following new and modified features:

	EV1000™ Clinical Platform NI (EV100NI)	**EV1000™ Clinical Platform (EV1000A)**
Technical Characteristics (Differences)	**New Features:** •Fluid Responsiveness Test screen •Manual Blood Pressure (BP) Calibration •ClearSight Workflow Options •Focused Screens	**New Features:** •Fluid Responsiveness Test screen (Passive Leg Raise and Fluid Bolus)

	Modified Features: •Optimization/Bug Fixes - Beat Detection Enhancements - Staircase Improvements •Enhanced error messaging/help screens • System identification of appropriate finger cuffs when connected to the EV1000NI platform •Heart Reference Sensor (HRS) EEPROM manufacturing date update •Cybersecurity •De-Identity Option in Data download •Flexible Alarm Standards Option (for China only, not subject of this 510(k))	**Modified Features:** •"Mini-Trends" and PPV added to HPI secondary screen •Existing PPV, Eadyn and dP/dt were added to the key parameter menu •Algorithm library (APCO) was updated for dP/dt, Eadyn, and PPV calculations •Cybersecurity •De-Identity Option in Data download •Flexible Alarm Standards Option (for China only, not subject of this 510(k))
Performance Data – 807.92(b)		
The following verification activities were performed in support of a substantial equivalence determination for the modifications being made as part of this submission.		
Nonclinical Test 807.92(b)(1)	**Software Verification** The EV1000 Clinical Platforms (EV1000A and EV1000NI) are considered as software of Moderate Level of Concern. Software verification was performed per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software on each of the individual modules was tested at a sub-system level to ensure the safety of the device. All tests passed. **System** Verification and Validation testing was conducted to compare the performance and functionality of the EV1000 Clinical Platforms (EV1000A and EV1000NI).The testing included side-by-side bench testing and a retrospective data analysis for algorithm and performance verification. Completion of all verification and validation activities demonstrated that the subject devices meet their predetermined design and performance specifications. Verification activities performed confirmed that the differences in the design and materials used did not adversely affect the safety and effectiveness of the subject device. Measured and derived parameters were tested using a bench simulation. Additionally, individual components were tested at a system level to verify the safety of these modules. They were also integrated as a system and verified for their safety and effectiveness. All tests passed. Therefore, the EV1000 Clinical Platforms were shown to be substantially equivalent to the predicate devices for its intended use in hospitals and other appropriate clinical environments.	

	Usability System validation of the EV1000 Clinical Platforms (EV1000A and EV1000NI) included an assessment by clinicians of its usability and human factors considerations. Usability tests for the new and modified features were performed and met all acceptance criteria. Therefore, the usability test was deemed as passed and the EV1000 Clinical Platforms met its intended use related to its primary operating function and did not create any confusion or use errors that could lead to unsafe conditions of use. The EV1000 Clinical Platforms remain in compliance with AAMI/ANSI/IEC 62366. **Electrical Safety and Electromagnetic Compatibility (EMC)** <u>EV1000A</u> Modifications do not require hardware changes to the EV1000A databox. Therefore, the EV1000A remains in compliance with Electrical Safety and Electromagnetic Compatibility (EMC) that have been previously reviewed and cleared by FDA in K160552. <u>EV1000NI</u> Confirmatory testing for EMC and Electrical Safety were performed as a result of minor changes made to the Heart Reference Sensor (HRS) and Pressure Controller (PC2K) components of the EV1000NI Platform to demonstrate equivalence to the predicate device. No other components were updated and therefore, these components remains in compliance with the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366-1, IEC 60601-2-34, IEC 60601-2-57 and IEC 60601-2-49 that have been previously reviewed and cleared by the FDA in K160552. All tests passed.
Clinical Test 807.92(b)(2)	A clinical study was not necessary to demonstrate equivalence to the predicate device.
Conclusion 807.92(b)(3)	Completion of all non-clinical activities demonstrated that the subject devices meet their predetermined design and performance specifications. The EV1000 Clinical Platform(s) have been shown to be substantially equivalent to the predicate devices for their intended use in hospitals and other appropriate clinical environments.