DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 1, 2016

Edwards Lifesciences, LLC
Tara Viviani
Principle Project Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K160552
Trade/Device Name: EV1000 Clinical Platform Non-Invasive (NI) and ClearSight Finger Cuffs or ClearSight System, EV1000 Clinical Platform
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG, DSB, DXN
Dated: May 25, 2016
Received: May 26, 2016

Dear Tara Viviani:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Shawn W. Forrest -S
2016.06.01 17:45:37 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160552

Device Name
EV1000 Clinical Platform Non-Invasive NI and ClearSightTM Finger Cuffs or
ClearSight™ System
EV1000 Clinical Platform

Indications for Use *(Describe)*

The EV1000 Clinical Platform NI and the ClearSightTM 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 non-invasive system is indicated for use in patients with co- morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform and the ClearSightTM finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

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.

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) 510(k)		
510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	Tara M. Viviani, RAC One Edwards Way M/S JAM B3 Irvine, CA 92614 tara_viviani@edwards.com (949) 250-4030	
Date Prepared	February 26, 2016	
Trade Name	EV1000 Clinical Platform™	EV1000 Clinical Platform™ NI with ClearSight™ Finger Cuffs or ClearSight™ System
Common Name	Cardiac Output / Oximetry Monitor	Non-Invasive Blood Pressure Measurement System
Classification Name	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) System, Measurement, Blood-Pressure, Non-Invasive (21 CFR 870.1130) Plethysmograph, Impedance (21 CFR 870.2770)
Regulation Class / Product Code	Class II DXG	Class II DXG, DXN, DSB
Predicate Device(s)	K131892 – EV1000 Clinical Platform (cleared 05/22/2014)	K140312 – EV1000 Clinical Platform™ NI with ClearSight™ Finger Cuffs or ClearSight™ System (cleared 06/13/2014)
Device Description	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 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. 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 (PC2) that is worn on the wrist, a Heart Reference Sensor (HRS), and the ClearSight™ Finger Cuffs. It may be attached to the patient bedside, an IV pole or roll stand.
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 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 non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform and the ClearSight™ finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.
Comparative Analysis	Verification and Validation testing was conducted to compare the performance and functionality of the EV1000 Clinical Platform and the EV1000 Clinical Platform with ClearSight Finger Cuffs to the predicate device. The testing included side-by-side bench testing and a clinical study. The EV1000 Clinical Platform(s) were shown to be safe, effective, and substantially equivalent to the predicate device for its intended use in hospitals and other appropriate clinical environments. The EV1000 Clinical Platform(s) use the same technology as the predicate devices with the added feature of providing a tool for the clinician to trend monitored parameters and compare them for compliance to a Goal Directed Therapy protocol. The trending features are Goal Directed Therapy protocol agnostic and may be used with reported parameters commonly used in Goal Directed Therapy.
Functional/ Safety Testing	The EV1000 Clinical Platform and the EV1000 Clinical Platform NI with ClearSight Finger cuffs have successfully passed functional and performance testing, including software verification and validation,

	mechanical and electrical testing, and bench studies. In addition, an evaluation of archived clinical data demonstrated that the device is substantially equivalent to the cited predicate device
Conclusion	The EV1000 Clinical Platform and the EV1000 Clinical Platform NI with ClearSight Finger cuffs have been shown to be safe, effective, and are substantially equivalent to the predicate devices for their intended use in hospitals and other appropriate clinical environments.