November 30, 2018

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

Re: K182245
Trade/Device Name: EV1000 Clinical Platform™ NI and the ClearSight™ Finger Cuffs or ClearSight™ System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DSB, DXG
Dated: August 17, 2018
Received: August 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 C. Browning -S5

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182245

Device Name
EV1000 Clinical Platform™ NI and the ClearSight™ Finger Cuffs or ClearSight™ System

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 or 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.

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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SECTION 5 – 510(k) SUMMARY

EV1000™ Clinical Platform NI and the ClearSight™ Finger Cuffs	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Christine J. Chun Manager, Regulatory Affairs Program Management Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250 – 2500 Fax: (949) 809 – 7303
Date Prepared	August 17, 2018
Trade Name	EV1000 Clinical Platform™ NI and the ClearSight™ Finger Cuffs or ClearSight™ System
Common Name	Non-Invasive Blood Pressure Measurement System
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive (21 CFR 870.1130) Plethysmograph, Impedance (21 CFR 870.2770) Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Regulation Class / Product Code	Class II DXN, DSB, DXG
Primary Predicate Device	K160552 – EV1000 Clinical Platform™ NI and the ClearSight™ Finger Cuffs or ClearSight™ System (cleared June 1, 2016).
Secondary Predicate (*for Packaging only*)	K140312 – EV1000 Clinical Platform with ClearSigh^{TM}t Finger Cuff or ClearSight™ System (cleared June 13, 2014).
Device Description	The EV1000 Clinical Platform NI and the ClearSight^{TM} Finger Cuffs is a non-invasive system that continuously measures 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 Clinical Platform NI and the ClearSight^{TM} Finger Cuffs 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 (EVHRS or also referred to as HRS), and the ClearSight^{TM} Finger Cuffs. EV1000M may be attached to the patient bedside, an IV pole or roll stand.

	The subject of this 510(k) is a change of the tubing material and its establishment of shelf life for the EVHRS, a component of the subject device, EV1000 Clinical Platform NI and the ClearSight Finger Cuff.
Indications for Use/Intended Use	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	The Heart Reference Sensor (EVHRS or may be referred to as HRS), a component/accessory of the subject device, EV1000 Clinical Platform NI and the ClearSight™ Finger Cuffs (also referred to as the EV1000NI, EV1000 Clinical Platform Non-Invasive, or the ClearSight™ System cleared under K160552 on June 01, 2016 and K140312 on June 13, 2014) has been modified by changing the inner tubing material from polyvinyl chloride (PVC) to an medical grade polyurethane plastic tubing material. No other changes have been made to the software, algorithm, hardware, and packaging or any other portion of the EV1000 Clinical Platform NI and the ClearSight Finger Cuffs.
Functional/ Safety Testing	The Heart Reference Sensor (EVHRS), accessory to the subject device, EV1000 Clinical Platform NI and the ClearSight™ Finger Cuff are identical to the predicate device in terms of intended use/indications for use, and technology. To ensure that the material change to the EVHRS did not raise any new concerns of safety and effectiveness, and is substantially equivalent to the predicate device, biocompatibility was conducted in accordance to ISO 10993-10 and functional testing was conducted to show performance is not affected. The EVHRS has been shown to be substantially equivalent to the predicate device for its intended use in hospitals and other appropriate clinical environments. The Heart Reference Sensor (EVHRS) accessory to the subject device, EV1000 Clinical Platform NI and the ClearSight™ Finger cuffs have successfully passed functional and performance testing, including mechanical, shelf life, biocompatibility, and bench studies, demonstrating that the subject device is substantially equivalent to the predicate device.

Conclusion	The Heart Reference Sensor (EVHRS), accessory to the subject device, EV1000 Clinical Platform NI and the ClearSight™ Finger cuffs are substantially equivalent to the predicate device for their intended use in hospitals and other appropriate clinical environments.