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5. 510(k) Summary

EV1000 CLINICAL PLATFORM 510(k) SUMMARY	
Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
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Date Prepared:	March 1, 2011
Trade name:	EV1000 Clinical Platform
Classification Name:	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Predicate Devices:	• K100709, Edwards Lifesciences LLC, EV1000 Platform • K082308, Edwards Lifesciences LLC, Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor • K072735, Pulsion Medical Systems, PiCCO-2
Device Description:	The EV1000 Clinical Platform consists of a Databox and Monitor components, which can be mounted to an IV pole. The EV1000 Clinical Platform measures patient physiologic parameters 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 Databox receives incoming signals from the patient through the connections provided by the accessories applied to the patient. The algorithms embedded in the Databox process the signals and provide parameter calculations. The EV1000 Monitor is connected to the Databox via an ethernet cable. The Monitor is a touchscreen, panel PC with a graphical user interface (GUI). The Monitor displays the measured and calculated parameter values from the Databox. The EV1000 Clinical Platform, when used with the VolumeView System, measures and/or calculates hemodynamic parameters such as:

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	• Auto-calibrated continuous parameters: cardiac output, cardiac index, stroke volume, stroke volume index, systemic vascular resistance, systemic vascular resistance index, and stroke volume variation; • Manual-calibrated continuous parameters: cardiac output, cardiac index, stroke volume, stroke volume index, systemic vascular resistance, systemic vascular resistance index, and stroke volume variation; and, • Manual-calibrated intermittent parameters: cardiac output , cardiac index, extravascular lung water, extravascular lung water index, global ejection fraction, global end-diastolic volume, global end-diastolic volume index, intrathoracic blood volume, pulmonary vascular permeability index, stroke volume, stroke volume index, systemic vascular resistance, and systemic vascular resistance index. When connected to a FloTrac sensor, the EV1000 Clinical Platform continuously measures/calculates arterial pressure cardiac output, cardiac index, stroke volume, stroke volume index, stroke volume variation, systemic vascular resistance, and systemic vascular resistance index. When connected to Edwards oximetry sensors, the EV1000 Clinical Platform continuously measures/calculates oximetry parameters.
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. 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.

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Comparative Analysis:	Verification and validation testing was conducted to compare the performance and functionality of the EV1000 Clinical Platform to the predicate devices. This testing regimen included head-to-head bench and pre-clinical studies, and comparative analysis of archived clinical data and clinical data obtained during a multi-center clinical trial of the EV1000 Clinical Platform. The EV1000 Clinical Platform has been shown to be safe and effective and substantially equivalent to the cited predicate devices for their intended use in the OR and ICU environments.
Functional/ Safety Testing:	The EV1000 Clinical Platform has successfully undergone functional and performance testing, including software verification and validation, mechanical and electrical testing, bench studies, pre-clinical animal studies, simulated comparison testing of archived clinical cases, clinical usability and human factor assessment and a multi-center clinical study. The EV1000 Clinical Platform has been shown to be safe and effective and substantially equivalent to the cited predicate devices for their intended use in the OR and ICU environments.
Conclusion:	The proposed EV1000 Clinical Platform is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Edwards Lifesciences, LLC
c/o Ms. Marguerite Thomlinson, J.D.
Sr. Manager of Regulatory Affairs, Critical Care
One Edwards Way
Irvine, CA 92614

JUN 14 2011

Re: K110597
Trade/Device Name: EV1000 Clinical Platform
Regulatory Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: II (two)
Product Code: DXG
Dated: May 13, 2011
Received: May 16, 2011

Dear Ms. Thomlinson:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110597

4. Indications for Use

510(k) Number (if known):

Device Name: EV1000 Clinical Platform

Indications for 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. 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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110597