K100709
p 1/2

DEC - 7 2010

510(k) Summary

Submitter: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614-5686

Contact Person: Patricia A. Milbank
Vice President, RA/CA

Date Prepared: November 29, 2010

Trade name: EV1000 Platform

Classification Name: Single-function, Preprogrammed Diagnostic Computer
(21 CFR 870.1435)

Predicate Devices: Edwards Lifesciences Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor; cleared under K082308
Pulsion PICCO-2 Monitor, cleared under K072735

Device Description: The EV1000 Platform consists of two components: a databox and a monitor. The databox is where all incoming signals are processed. It contains all the algorithms for parameter calculation. It is mounted to the patient bedside or to an IV pole. The databox has mounts so that pressure transducers, FloTrac sensors, and the VolumeView System can be attached to it. The databox has no graphical user interface. It connects, via an Ethernet cable, to the EV1000 monitor.

The EV1000 monitor is a panel PC with a touchscreen interface. It is connected to the databox by an Ethernet cable. It is intended to be mounted to an IV pole. The monitor does not process any data; its sole function is to act as a user and communication interface.

The EV1000 Platform, when connected to the VolumeView system, intermittently measures or calculates intermittent cardiac output, intermittent cardiac index, , intermittent stroke volume, intermittent stroke volume index, systemic vascular resistance, and systemic vascular resistance index.

When connected to a FloTrac sensor, the platform continuously measures or calculates arterial pressure cardiac output, stroke volume, stroke volume index, stroke volume variation, systemic vascular resistance, and systemic vascular resistance index.

K100709
p2/2

510(k) Summary

Intended Use:	The EV1000 Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs constant or intermittent assessment. The EV1000 Platform may be used in all settings in which critical care is provided.
Comparative Analysis:	The EV1000 Platform has been demonstrated to be as safe and effective as the predicate devices for their intended use.
Functional/Safety Testing:	The EV1000 Platform has successfully undergone functional testing. This product has been shown to be equivalent to the predicate devices.
Conclusion:	The proposed EV1000 Platform 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. Patricia Milbank, J.D.
Vice President, RA/CA, Critical Care
One Edwards Way
Irvine, CA 92614

DEC - 7 2010

Re: K100709

Trade/Device Name: EV1000 Platform
Regulatory Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: II (two)
Product Code: DXG
Dated: November 19, 2010
Received: November 22, 2010

Dear Ms. Milbank:

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

K100709

Indications for Use Statement

DEC - 7 2010

510(k) Number (if known): K100709

Device Name: EV1000 Platform

Indications for Use:

The EV1000 Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs constant or intermittent assessment. The EV1000 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 807 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 K100709