MAY 2 2 2014

SECTION 5 - 510(K) SUMMARY

VIGILEO™ MONITOR 510(k) SUMMARY	
510(k) Submitter	Edwards Lifesciences
Contact Person	Sally L. Maher One Edwards Way Irvine, CA 92614-5686
Date Prepared	May 6, 2014
Trade Name	Vigileo™ Arterial Pressure Cardiac Output (APCO)/Oximetry Monitor
Common Name	Cardiac Output/Oximetry Computer
Classification Name	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435, product codes DXG, DQE)
Regulation Class/ Product Code	Class II/ DXG, DQE
Predicate Device	K103094 (cleared 17 March 2011), Edwards Lifesciences, Vigileo™ Arterial Pressure Cardiac Output/Oximetry Monitor
Device Description	The Vigileo™ Arterial Pressure Cardiac Output (APCO)/Oximetry Monitor (Vigileo™ Monitor) is a microprocessor-based instrument. When used with an Edwards FloTrac sensor, the Vigileo™ Monitor is capable of continuously monitoring the following parameters: • Cardiac Output (CO); • Cardiac Index (CI); • Stroke Volume (SV); • Stroke Volume Variation (SVV); • Systemic Vascular Resistance (SVR); • Systemic Vascular Resistance Index (SVRI); • Oxygen Delivery (DO_2); and • Oxygen Delivery Index (DO_2I). When used with Edwards Oximetry catheters, the Vigileo™ Monitor is capable of continuously monitoring the following parameters: • Central venous oxygen saturation ($ScvO_2$); and, • Mixed venous oxygen saturation (SvO_2).

VIGILEO™ MONITOR 510(k) SUMMARY, con't.	
Indications for Use/ Intended Use	The Vigileo™ APCO/Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The monitor also displays parameters, such as stroke volume and stroke volume variation, used to assess fluid status and vascular resistance. The Vigileo™ APCO/Oximetry Monitor may be used in all setting in which critical care is provided.
Comparative Analysis	Verification and validation testing was conducted to compare the performance and functionality of the subject and predicate devices. This testing regimen included side-by-side bench, pre-clinical studies, and comparative analysis of clinical data. The Vigileo™ Monitor has been shown to be safe, effective, and substantially equivalent to the cited predicate device for its intended use critical care environments.
Functional/ Safety Testing	The Vigileo™ Monitor has successfully passed functional and performance testing, including software verification and validation, mechanical and electrical testing, bench studies, pre-clinical animal studies, comparison testing of clinical cases, and clinical utility.
Conclusion	The Vigileo™ Monitor has been shown to be safe, effective, and is substantially equivalent to the cited predicate devices for their intended use in the OR and ICU environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 22, 2014

Edwards Lifesciences LLC
Mr. Stephen M. Enos
Director, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K131588
Edwards Lifesciences™ Vigileo™ Arterial Pressure Cardiac Output/Oximetry Monitor
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DXG, DQE
Dated: May 6, 2014
Received: May 7, 2014

Dear Mr. Enos:

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.

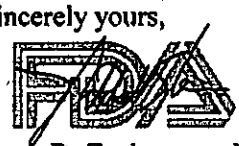
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 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. 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,



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)*
K131588

Device Name

Edwards Lifesciences™ Vigileo™ Arterial Pressure Cardiac Output/Oximetry Monitor

Indications for Use *(Describe)*

The Vigileo™ APCO/Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics.

The monitor also displays parameters, such as stroke volume and stroke volume variation, used to assess fluid status and vascular resistance. The Vigileo™ APCO/Oximetry Monitor 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA Date: 2014.05.22 11:18:12 -04'00'

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