DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2017

Edwards Lifesciences, LLC
Chirag Shah
Associate Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K163381
Trade/Device Name: HemoSphere Advanced Monitor, HemoSphere Swan-ganz Module, HemoSphere Oximetry Cable
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE
Dated: March 15, 2017
Received: March 16, 2017

Dear Chirag Shah:

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,

Fernando Aguel -S

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)*
K163381

Device Name
HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable

Indications for Use *(Describe)*

HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module

The HemoSphere Advanced Monitor when used with the HemoSphere Swan-Ganz Module and Edwards Swan-Ganz Catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output [continuous (CO) and intermittent (iCO)] and derived hemodynamic parameters in a hospital environment. Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

The HemoSphere Advanced Monitor when used with the HemoSphere Oximetry Cable and Edwards oximetry catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of venous oxygen saturation (SvO2 and ScvO2) and derived hemodynamic parameters in a hospital environment. Refer to the Edwards oximetry catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

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

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Chirag Shah Associate Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 Telephone: (949) 250-1580 Fax: (949) 809-2972
Date:	November 30, 2016
Platform Name	HemoSphere Advanced Monitoring Platform
Trade Name:	HemoSphere Advanced Monitor HemoSphere Swan-Ganz Module HemoSphere Oximetry Cable
Common Name:	Cardiac Output/Oximetry/Ejection Fraction Computer
Classification Name:	Programmable Diagnostic Computer 21 CFR 870.1425 Fiberoptic Oximeter Catheter 21 CFR 870.1230
Product Code:	DQK, Class II DQE, Class II
Primary Predicate Device:	Vigilance II Continuous Cardiac Output/Oximetry/Volumetric (CCO/SvO_2/CEDV) Monitor manufactured by Edwards Lifesciences, K043103, cleared December 9, 2004.
Secondary Predicate Device:	EV1000 Clinical Platform manufactured by Edwards Lifesciences, K160552, cleared June 01, 2016.
Device Description:	The HemoSphere Advanced Monitoring Platform is a modular system which uses the same monitoring technology (CCO, ICO, Oximetry), the same associated devices (Swan-Ganz and Oximetry Catheters), the same analog inputs from external vital sign monitors, the same computational algorithms for hemodynamic monitoring and the same default alarm limits as the Vigilance II System

(K043103, cleared December 9, 2004). Updates made to the HemoSphere Advanced Monitoring Platform include a modernized look (updated Graphical User Interface (GUI) and touchscreen monitor), wireless capability, a modular architecture for scalability and two new derived oximetry parameters. The updated GUI is similar to the GUI utilized in the EV1000 Clinical Platform (K160552, cleared June 01, 2016). The two new derived oximetry parameters (Estimated Oxygen Consumption (VO2e) and Estimated Oxygen Consumption Index (VO2Ie)) are derived parameters that are currently available on the EV1000 Clinical Platform (K160552, cleared June 01, 2016).

The HemoSphere Advanced Monitoring Platform consists of the HemoSphere Advanced Monitor that provides a means to interact with and visualize hemodynamic and volumetric data on a screen and two optional external modules: the HemoSphere Swan-Ganz Module and the HemoSphere Oximetry Cable.

These optional modules provide an interface to connect with currently cleared and commercially available Edwards Lifesciences Swan-Ganz and Oximetry catheters (K803058, K822350, K905458, K924650, K934742, K940795, K053609 and K110167 and K160884). The modules provide the software technology to compute hemodynamic monitoring data that is then sent to the monitor for visualization and storage.

The HemoSphere Advanced Monitor has an input that can be connected to an external vital sign patient monitor for the purpose of slaving in an analog ECG signal. The HemoSphere Platform uses this analog ECG input signal to calculate a heart rate that is used by the HemoSphere Swan-Ganz Module to calculate certain derived parameters (e.g. HRavg, SV, RVEF and EDV).

Indications for Use:

HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module

The HemoSphere Advanced Monitor when used with the HemoSphere Swan-Ganz Module and Edwards Swan-Ganz Catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output [continuous (CO) and intermittent (iCO)] and derived hemodynamic parameters in a hospital environment. Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

The HemoSphere Advanced Monitor when used with the HemoSphere Oximetry Cable and Edwards oximetry catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of venous oxygen saturation (SvO_2 and $ScvO_2$) and derived hemodynamic parameters in a hospital environment. Refer to the Edwards oximetry catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

Intended Use:

The HemoSphere Advanced Monitoring Platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

The HemoSphere Advanced Monitoring Platform is intended for use with the Edwards Swan-Ganz and Oximetry Catheters.

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere Swan-Ganz module are listed in the table below. Only iCO, iCI, iSVR, and iSVRI are available to the pediatric patient population

Parameters	Description	Patient Population
CO	continuous cardiac output	Adult only
sCO	STAT cardiac output	
CI	continuous cardiac index	
sCI	STAT cardiac index	
EDV	right ventricular end diastolic volume	
sEDV	STAT right ventricular end diastolic volume	
EDVI	right ventricular end diastolic volume index	
sEDVI	STAT right ventricular end diastolic volume index	
HR_{avg}	averaged heart rate	
LVSWI	left ventricular stroke work index	
PVR	pulmonary vascular resistance	
PVRI	pulmonary vascular resistance index	
RVEF	right ventricular ejection fraction	

sRVEF	STAT right ventricular ejection fraction	
RVSWI	right ventricular stroke work index	
SV	stroke volume	
SVI	stroke volume index	
SVR	systemic vascular resistance	
SVRI	systemic vascular resistance index	
iCO	intermittent cardiac output	Adult and Pediatric
iCI	intermittent cardiac index	
iSVR	intermittent systemic vascular resistance	
iSVRI	intermittent systemic vascular resistance index	

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Advanced Monitor and a connected HemoSphere oximetry cable are as listed below:

Parameters	Description	Patient Population
SvO2	Mixed Venous Oxygen Saturation	Adult and Pediatric
ScvO2	Central Venous Oxygen Saturation	

A comprehensive list of additional parameters that are available for adult and pediatric patient populations on the HemoSphere Advanced Monitor when connected with the HemoSphere Swan-Ganz Module and the HemoSphere Oximetry Cable are as listed below:

Parameters	Description	Patient Population
DO2	Oxygen Delivery	Adult and Pediatric
DO2I	Oxygen Delivery Indexed	
VO2	Oxygen Consumption	
VO2e	Estimated Oxygen Consumption when ScvO2 is being monitored	
VO2I	Oxygen Consumption Index	
VO2Ie	Estimated Oxygen Consumption Index when ScvO2 is being monitored	

Comparison to Predicate Device:

The HemoSphere Advanced Monitoring Platform is a modular platform which uses the same monitoring technology (CCO, ICO, Oximetry), the same associated catheters (Swan-Ganz and Oximetry Catheters), the same analog inputs from external vital sign monitors, the same computational algorithms for hemodynamic monitoring and the same default alarm limits as Vigilance II System (K043103, cleared December 9, 2014).

Updates made to the HemoSphere Advanced Monitoring Platform include a modernized look (updated Graphical User Interface (GUI) and touchscreen monitor), wireless capability, a modular architecture designed for scalability, and two additional derived oximetry parameters (Estimated Oxygen Consumption (VO_2e) and Estimated Oxygen Consumption Index (VO_2Ie)). The updated GUI is similar to the GUI utilized in the EV1000 Clinical Platform (K160552, cleared June 01, 2016). Wireless capabilities for the HemoSphere Advanced Monitoring Platform are limited to connecting and sending data to external Medical Device Data Systems. The two additional derived oximetry parameters (VO_2e and VO_2Ie) are derived parameters that are currently available on the EV1000 Clinical Platform.

The HemoSphere Advanced Monitor has an HDMI display output port to connect to an external monitor as opposed to a VGA port on the Vigilance II System. All other input and output ports remain the same.

The HemoSphere Advanced Monitor is built on a Windows 7 Operating System whereas the Vigilance II System used a Nucleus Real Time Operating System (RTOS).

Verification and validation testing was performed to compare the performance and functionality of the HemoSphere Advanced Monitoring Platform and the Vigilance II System. Testing included a side-by-side comparison of the output parameters using a bench test.

Performance Data (Bench and/or Clinical):

The following verification activities were performed in support of a substantial equivalence determination.

System Verification

Key Cardiac Output parameters (ICO, CCO, RVEF, Blood Temperature and Injectate Temperature) and Oximetry parameters (SvO_2 and $ScvO_2$) were tested using a bench simulation. Power switching and shutoff verification for the Swan-Ganz module was performed. Additionally, individual modules were tested at a system level to verify the safety of these modules. They were also integrated as a system and verified for their safety and effectiveness.

Electrical Safety and Electromagnetic Compatibility (EMC)
The HemoSphere Advanced Monitor, The HemoSphere Swan-Ganz Module and the HemoSphere Oximetry Cable were tested to the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366 and IEC 60601-2-49.

Wireless Coexistence Testing
Bench and simulated environment testing was performed on the HemoSphere Advanced Monitoring Platform.

Software Verification
The HemoSphere Advanced Monitor and the HemoSphere Oximetry Cable were both considered as software of Moderate Level of Concern. The HemoSphere Swan-Ganz Module was considered as software of Major Level of Concern.

Software verification was performed per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software on each of the individual modules was tested at a sub-system level to ensure the safety of the device.

Animal Study
An animal study involving 4 pigs and 25 clinicians was performed to verify usability of the HemoSphere Advanced Monitoring Platform.

Clinical Performance
Clinical data was not required for this device.

Conclusions

Non-Clinical Performance Conclusions:
Completion of all verification and validation activities demonstrated that the subject devices meet their predetermined design and performance specifications. Verification activities performed confirmed that the differences in the design and materials used did not adversely affect the safety and effectiveness of the subject device.

Clinical Performance Conclusions:
Clinical data was not required for this device.

Overall Conclusion:
The nonclinical and clinical tests demonstrate that the HemoSphere Advanced Monitoring Platform (the HemoSphere Advanced Monitor, the HemoSphere Swan-Ganz Module and the HemoSphere Oximetry Cable) is substantially equivalent to the legally marketed predicate Vigilance II System.