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

November 16, 2018

Re: K180881
Trade/Device Name: HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, Acumen Hypotension Prediction Index feature
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ
Dated: October 16, 2018
Received: October 17, 2018

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. 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)*
K180881

Device Name
HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable and Acumen Hypotension Prediction Index feature

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.

HemoSphere Advanced Monitor with HemoSphere Pressure Cable
The HemoSphere Advanced Monitor when used with the HemoSphere Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac, FloTrac IQ and TruWave DPT sensor indications for use statement for information on target patient population specific to the sensor being used.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in operating room (OR) patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Hypotension Prediction Index (HPI) parameter.

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 Program Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 Telephone: (949) 250-1580 Fax: (949) 809-2972
Date:	November 13, 2018
Platform Name	HemoSphere Advanced Monitoring Platform
Trade Name:	HemoSphere Advanced Monitor HemoSphere Swan-Ganz Module HemoSphere Oximetry Cable HemoSphere Pressure Cable Acumen Hypotension Prediction Index feature
Common Name:	Cardiac Output/Oximetry/Ejection Fraction Computer
Classification Name:	Programmable Diagnostic Computer 21 CFR 870.1425 Fiberoptic Oximeter Catheter 21 CFR 870.1230 Adjunctive Predictive Cardiovascular Indicator 21 CFR 870.2210
Product Code:	DQK, Class II DQE, Class II QAQ, Class II
Primary Predicate Device:	HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K163381, cleared on April 14, 2017.
Additional Predicate Devices:	EV1000A Clinical Platform manufactured by Edwards Lifesciences, K160552, cleared June 01, 2016.

Acumen Hypotension Prediction Index (HPI) feature on EV1000A Clinical Platform manufactured by Edwards Lifesciences, DEN160044, granted on March 16, 2018.

Philips IntelliVue MP50 manufactured by Philips Medizin Systeme Boeblingen GmbH, K053522, cleared on January 10, 2006 utilized for the parameter; Mean Pulmonary Arterial Pressure (MPAP).

Philips IntelliVue Patient Monitor MP50 manufactured by Philips Medizin Systeme Boeblingen GmbH, K062283, cleared on September 20, 2006 utilized for the parameter; Pulse Pressure Variation (PPV).

Device Description:

The HemoSphere Advanced Monitoring platform was designed to simplify the customer experience by providing one platform with modular solutions for their hemodynamic monitoring needs. The user can choose from the available optional sub-system modules or use multiple sub-system modules at the same time. This modular approach provides the customer with the choice of purchasing and/or using specific monitoring applications based on their needs. Users are not required to have all of the modules installed at the same time for the platform to function.

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 three optional external modules: the HemoSphere Swan-Ganz Module (existing), the HemoSphere Oximetry Cable (existing) and the HemoSphere Pressure Cable (new to the platform). This version of the platform also includes the Acumen Hypotension Prediction Index feature.

The existing optional modules provide an interface to connect with currently cleared and commercially available Edwards Lifesciences Swan-Ganz catheters and Oximetry catheters (K803058, K822350, K905458, K924650, K934742, K940795, K053609 and K110167 and K160884).

The new HemoSphere Pressure Cable provides an interface to connect with currently cleared and commercially available Edwards Lifesciences FloTrac (K152980), FloTrac IQ (K152980) and TruWave DPT sensors (K142749).

All the sub-system modules provide the hardware and software technology to compute hemodynamic monitoring data that is then sent to the HemoSphere Advanced Monitor for visualization and storage.

As cleared under K163381 on April 14, 2017, 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 and pressure signals. 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).

The HemoSphere Advanced Monitor when used with the HemoSphere Pressure Cable (new to the HemoSphere platform) uses the same monitoring technology (pressure and pressure based Cardiac Output), the same computational algorithms and the same default alarm limits as the EV1000A Clinical Platform (K160552, cleared June 1, 2016).

The HemoSphere Pressure Cable also enables the Acumen Hypotension Prediction Index (HPI) feature when connected to a FloTrac IQ sensor similar to the EV1000A Clinical Platform (DEN160044, granted March 16, 2018).

The HemoSphere Pressure Cable when connected to a TruWave DPT sensor and a compatible Edwards Advanced Swan-Ganz catheter allows monitoring of a new parameter; Mean Pulmonary Arterial Pressure (MPAP).

Additionally, a HemoSphere Pressure-Out cable has been developed for the HemoSphere Advanced Monitor. This cable enables output of analog pressure signals (MAP, CVP or PAP) for display on an external patient monitor.

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.

HemoSphere Advanced Monitor with HemoSphere Pressure Cable
The HemoSphere Advanced Monitor when used with the HemoSphere Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac, FloTrac IQ and TruWave DPT sensor indications for use statement for information on target patient population specific to the sensor being used.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in operating room (OR) patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Hypotension Prediction Index (HPI) parameter.

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 and FloTrac, FloTrac IQ and TruWave DPT sensors.

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.

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO	continuous cardiac output	HemoSphere Swan-Ganz Module	Adult only	Operating Room, Intensive Care Unit, Emergency Room
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:

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
SvO2	Mixed Venous Oxygen Saturation	HemoSphere Oximetry Cable	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
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:

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
DO2	Oxygen Delivery	HemoSphere Swan-Ganz Module and HemoSphere Oximetry Cable	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
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			

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO/CI	Continuous Cardiac Output/ Continuous Cardiac Index	HemoSphere Pressure Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
CVP	Central Venous Pressure			
DIA	Diastolic Blood Pressure			
dP/dt	Maximal slope of the arterial pressure upstroke			
Ea_{dyn}	Dynamic Arterial Elastance			
MAP	Mean Arterial Pressure			
MPAP	Mean Pulmonary Arterial Pressure			
SV/SVI	Stroke Volume/Stroke Volume Index			
SVR/SVRI	Systemic Vascular Resistance/ Systemic Vascular Resistance Index			
SVV	Stroke Volume Variation			
SYS	Systolic Blood Pressure			
HPI	Acumen Hypotension Prediction Index			Operating Room Only

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
DO2	Oxygen Delivery	HemoSphere Swan-Ganz Module and HemoSphere Oximetry Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
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 existing HemoSphere Advanced Monitoring Platform (K163381, cleared April 14, 2017) consists of:

- HemoSphere Advanced Monitor
- HemoSphere Swan-Ganz Module
- HemoSphere Oximetry Cable

This 510(k) submission adds the following to the HemoSphere Advanced Monitoring Platform:

- HemoSphere Pressure Cable
- Acumen Hypotension Prediction Index feature
- HemoSphere Pressure-Out Cable (a new accessory)
- New key parameter; Mean Pulmonary Arterial Pressure (MPAP)

Modifications to existing elements include:

- Graphical User Interface updates to the Sentinel Host Module of the HemoSphere Advanced Monitor
- Software modifications to the Data Bridge Module of the HemoSphere Advanced Monitor
- Algorithm updates for the Acumen Hypotension Prediction Index parameters (display only); Stroke Volume Variation (SVV), Dynamic Elastance (Ea_{dyn}) and Left Ventricular Contractility (dP/dt)

The following predicates are used to establish substantial equivalence:

- Primary Predicate: HemoSphere Advanced Monitor (K163381, cleared April 14, 2017) utilized for substantial equivalence to the HemoSphere Advanced Monitor in terms of the graphical user interface (GUI) used, wireless module incorporated, device modularity and basic device functionality
- Additional Predicate: EV1000A Clinical Platform (K160552, cleared June 1, 2016) utilized for substantial equivalence to the HemoSphere Pressure Cable in terms of key parameters (pressure and arterial pressure based cardiac output) and derived hemodynamic parameters when connected to previously cleared Edwards FloTrac (K152980), FloTrac IQ (LTF to K152980) and TruWave DPT sensors (K142749)Additional Predicate: Acumen Hypotension Prediction Index feature (DEN160044, granted March 16, 2018) utilized for substantial equivalence to the Acumen Hypotension Prediction Index feature, including all its parameters and secondary screens
- Additional Predicate: Philips IntelliVue Patient Monitor MP50 manufactured by Philips Medizin Systeme Boeblingen GmbH, K053522, cleared on January 10, 2006 utilized for the parameter; Mean Pulmonary Arterial Pressure (MPAP)
- Additional Predicate: Philips IntelliVue Patient Monitor MP50 manufactured by Philips Medizin Systeme Boeblingen GmbH,

K062283, cleared on September 20, 2006 utilized for the parameter; Pulse Pressure Variation (PPV)

The HemoSphere Advanced Monitoring Platform when used with the HemoSphere Swan-Ganz Module and the HemoSphere Oximetry Cable allows for monitoring of hemodynamic parameters, including continuous and intermittent cardiac output, right ventricular ejection fraction, end diastolic volume and mixed or central venous oxygen saturation along with additional calculated parameters as cleared in K163381 on April 14, 2017.

A new sub-system module; the HemoSphere Pressure Cable is being added to allow for monitoring of pressure and arterial pressure based cardiac output along with Acumen Hypotension Prediction Index (HPI) feature. The HemoSphere Pressure Cable also calculates additional derived parameters based on the key monitored parameters. The HemoSphere Pressure Cable when used with the HemoSphere Advanced Monitor uses the same associated sensors (FloTrac, FloTrac IQ and TruWave), the same analog inputs from external vital sign monitors, the same computational algorithms for hemodynamic monitoring and the same default alarm limits as the EV1000A Clinical Platform (K160552 cleared on June 1, 2016). The HPI feature is similar to that granted in DEN160044 on March 2018.

The HemoSphere Pressure Cable uses the HPI feature as granted in DEN160044, including the algorithms, secondary screens and graphical user interface with some waveform smoothing modifications made to the Pulse Pressure Variation (PPV) and Left Ventricular Contractility (dP/dt) algorithms for display purposes only.

Additional modifications were made to the Graphical User Interface of the HemoSphere Advanced Monitor (K163381, cleared April 14, 2017) to support two different modes: Invasive and Minimally-Invasive modes based on the sub-system module being used. Clinical Data Logging feature was added to collect sub-system module data for internal technical analysis.

The HemoSphere Pressure Cable when connected to a TruWave DPT sensor and a compatible Edwards Advanced Swan-Ganz catheter allows monitoring of a new parameter that is not available on the EV1000A Clinical Platform (K160552, cleared June 1, 2016); Mean Pulmonary Arterial Pressure (MPAP).

In addition, a HemoSphere Pressure-Out Cable has been developed to output Mean Arterial Pressure (MAP), Central Venous Pressure (CVP) or Pulmonary Arterial Pressure (PAP) signals to an external patient monitor.

Verification and validation testing was performed to compare the performance and functionality of the HemoSphere Advanced Monitor when used with a HemoSphere Pressure Cable and the EV1000 Clinical Platform. 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 for the modifications being made as part of this submission.

System Verification
Measured parameters (pressure and pressure based cardiac output) were tested using a bench simulation. 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. All tests passed.

Electrical Safety and Electromagnetic Compatibility (EMC)
The HemoSphere Advanced Monitor and the HemoSphere Pressure 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, IEC 60601-2-34 and IEC 60601-2-49. All tests passed.

Wireless Coexistence Testing
Bench and simulated environment testing was performed on the entire HemoSphere Advanced Monitoring Platform, including all sub-system modules and interfacing analog inputs and outputs. All tests passed.

Software Verification
The HemoSphere Advanced Monitor and HemoSphere Swan-Ganz Module are considered as software of Major Level of Concern. The HemoSphere Oximetry Cable and HemoSphere Pressure Cable are considered as software of Moderate 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. All tests passed.

Usability Study
A usability study was performed for the HemoSphere Advanced Monitoring Platform, including software changes and changes to the Acumen Hypotension Prediction Index feature in accordance with FDA's guidance, "Applying Human Factors and Usability Engineering to Medical Devices". Testing involved 32 users with a mix of clinicians and nurses. Test Passed.

Clinical Performance
Clinical data was not required for this device.

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.

Conclusions

Overall Conclusion:
The nonclinical and clinical tests demonstrate that the HemoSphere Advanced Monitoring Platform (the HemoSphere Advanced Monitor, the HemoSphere Swan-Ganz Module, the HemoSphere Oximetry Cable, the HemoSphere Pressure Cable and the Acumen Hypotension Prediction Index feature) are substantially equivalent to the legally marketed predicates.