November 7, 2022

Edwards Life Sciences LLC
Varad Raghuwanshi
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K221833
Trade/Device Name: HemoSphere Advanced Monitor. HemoSphere SwanGanz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module, HemoSphere ClearSight Module
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DSB, DQK, DQE, MUD
Dated: June 21, 2022
Received: June 23, 2022

Dear Varad Raghuwanshi:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221833

Device Name
HemoSphere Advanced Monitor. HemoSphere SwanGanz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module, HemoSphere ClearSight Module

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. It may also be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol 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 below 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, Acumen 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 surgical and non-surgical 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.

HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module:

The noninvasive FORE-SIGHT ELITE tissue oximeter module is intended for use as an adjunct monitor for absolute regional hemoglobin oxygen saturation of blood under the Sensors in individuals at risk for reduced-flow or no-flow ischemic states. The FORE-SIGHT ELITE tissue oximeter module is intended to allow for the display of StO2 on the HemoSphere advanced monitor.

- When used with large sensorsis indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on pediatric subjects ≥3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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 ClearSight Module:

The HemoSphere Advanced Monitor when used with the HemoSphere ClearSight module, pressure controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters.

Refer to the ClearSight finger cuff indications for use statements for information on target patient population specific to the finger cuff being used

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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510(k) Summary – HemoSphere Advanced Monitoring Platform

I. Submitter:

Sponsor: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

Establishment Registration Number: 2015691

Contact Person: Varad Raghuwanshi
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One Edwards Way
Irvine, CA 92614
Telephone: (949) 756-4502
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Date Prepared: October 8, 2022

II. Device Information:

Platform Name (Name of the Device) HemoSphere Advanced Monitoring Platform

Trade Name:
HemoSphere Advanced Monitor
HemoSphere Swan-Ganz Module
HemoSphere Oximetry Cable
HemoSphere Pressure Cable
HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module
HemoSphere ClearSight Module

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
Oximeter	21 CFR 870.2700
Noninvasive blood pressure measurement system	21 CFR 870.1130
Impedance plethysmograph	21 CFR 870.2770

Product Code and Regulatory Class:	DQK, Class II DQE, Class II QAQ, Class II MUD, Class II DXN, Class II DSB, Class II

III. Predicate Device

Primary Predicate Device:	HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K201446 cleared October 1, 2020.

IV. Device Description

Device Description:	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 five (5) optional external modules: the HemoSphere Swan-Ganz Module (K163381 Cleared, April 14, 2017), the HemoSphere Oximetry Cable (K163381 Cleared, April 14, 2017), HemoSphere Pressure Cable (K180881 Cleared, November 16, 2018), HemoSphere Tissue Oximetry Module (K190205 August 29, 2019), and the HemoSphere ClearSight Module (K201446 Cleared October 1, 2020).

V. Indications for Use:

***Note:* There is no change to the Indication for Use statements from what was cleared in K201446 on October 1, 2020.**

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. It may also be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol 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 below 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, Acumen 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 surgical 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.

HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module

The non-invasive FORE-SIGHT ELITE tissue oximeter module is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the Sensors in individuals at risk for reduced-flow or no-flow ischemic states. The FORE-SIGHT ELITE tissue oximeter module is intended to allow for the display of StO_2 on the HemoSphere advanced monitor.

- When used with large sensors, is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on pediatric subjects ≥3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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 ClearSight Module

The HemoSphere Advanced Monitor when used with the HemoSphere ClearSight module, pressure controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters.

Refer to the ClearSight finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

Intended Use: ***Note: There is no change to the Intended use from what was cleared in K201446 on October 1, 2020.***

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 compatible Edwards Swan-Ganz and oximetry catheters, FloTrac sensors, Acumen IQ sensors, TruWave DPTs, ForeSight Elite sensors, and ClearSight finger cuffs.

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere Swan-Ganz module are listed 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 parameters available for adult and pediatric patient populations while monitoring with the HemoSphere advanced monitor and both a connected HemoSphere Swan-Ganz module and oximetry cable are 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[1]/ Continuous Cardiac Index[1]	HemoSphere Pressure Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
CVP	Central Venous Pressure			
DIA_{ART}	Systemic arterial diastolic blood pressure			
DIA_{PAP}	pulmonary artery diastolic blood pressure			
dP/dt	Systolic slope[2]			
Ea_{dyn}	Dynamic Arterial Elastance[2]			
MAP	Mean Arterial Pressure			
MPAP	Mean Pulmonary Arterial Pressure			
PPV	pulse pressure variation[1]			
PR_{ART}	Pulse rate			
SV/ SVI	Stroke Volume[1]/ Stroke Volume Index[1]			

SVR/ SVRI	Systemic Vascular Resistance[1]/ Systemic Vascular Resistance[1] Index			
SVV	Stroke Volume Variation[1]			
SYS	Systolic Blood Pressure			
HPI	Acumen Hypotension Prediction Index			
[1]FloTrac parameters are available when using a FloTrac/Acumen IQ sensor and if the FloTrac feature is enabled. *[2]HPI parameters are available when using an Acumen IQ sensor and if the HPI feature is activated.*				

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**
DO_2	Oxygen Delivery	HemoSphere Swan-Ganz Module and HemoSphere Oximetry Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
DO_2I	Oxygen Delivery Indexed			
VO_2	Oxygen Consumption			
VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored			
VO_2I	Oxygen Consumption Index			
VO_2Ie	Estimated Oxygen Consumption Index when $ScvO_2$ is being monitored			

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and both a connected HemoSphere Swan-Ganz Module and a connected HemoSphere pressure cable are as listed below.

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO_{20s}	20-second cardiac output	HemoSphere Swan-Ganz module and HemoSphere pressure cable	Adult only	Operating room, intensive care unit, emergency room
CI_{20s}	20-second cardiac index			
SV_{20s}	20-second stroke volume			
SVI_{20s}	20-second stroke volume index			

Tissue oxygen saturation, StO2, can be monitored with the HemoSphere Advanced Monitor, a connected HemoSphere Tissue Oximetry Module, and the FORE-SIGHT ELITE Tissue Oximeter Module. Refer to the FORE-SIGHT ELITE HemoSphere Advanced Monitoring Platform

Operators Manual for specific information on the intended use environment and patient population.

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
StO_2	Tissue oxygen saturation	HemoSphere Tissue Oximetry Module and Fore-Sight Elite Module	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere ClearSight module are listed below

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO/CI	Continuous Cardiac Output/ Continuous Cardiac Index	HemoSphere ClearSight Module	Adult only	Operating Room, Intensive Care Unit, Emergency Room
DIA	Noninvasive arterial diastolic blood pressure			
MAP	Noninvasive Mean Arterial Pressure			
PPV	pulse pressure variation			
PR	Noninvasive Pulse rate			
SV/ SVI	Stroke Volume/ Stroke Volume Index			
SVR/ SVRI	Systemic Vascular Resistance Systemic Vascular Resistance Index			
SVV	Stroke Volume Variation			
SYS	Systolic Blood Pressure			

A comprehensive list of parameters available for adult patient populations while monitoring with the HemoSphere advanced monitor and both a connected HemoSphere ClearSight module and oximetry cable are listed below

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
DO_2	Oxygen Delivery	HemoSphere ClearSight Module and HemoSphere Oximetry Cable	Adult only	Operating Room, Intensive Care Unit
DO_2I	Oxygen Delivery Indexed			
VO_2	Oxygen Consumption			
VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored			
VO_2I	Oxygen Consumption Index			
VO_2Ie	Estimated Oxygen Consumption Index when $ScvO_2$ is being monitored			

VI. Comparison of Technological Characteristics with the Predicate Devices:

The intended use, indications for use, instructions and technological characteristics of the modified device remain unchanged. The following section provides a summary of the modification.

The purpose of this 510(k) submission is to introduce the following modification to the HemoSphere Advanced Monitoring Platform (Cleared in K201446 on October 1, 2020):

- Modification to the existing APCO algorithm of the HemoSphere ClearSight™ Module

  The existing HemoSphere ClearSight Module includes the APCO algorithm (Arterial pressure-based Cardiac Output) to calculate Cardiac Output and derived parameters. As a part of Edwards's continuous improvement efforts, a modification has been made to improve the existing bias in the currently cleared APCO algorithm.

Performance Data:

The following verification activities were performed to evaluate the modification being made as part of this submission. Pass/Fail criteria were based on the specifications cleared for the predicate devices, and test results showed substantial equivalence.

There is no change in the electromagnetic compatibility, electrical safety, environmental (including Mechanical stress testing and Package Testing), and usability compared to the predicate.

Algorithm Verification (Clinical Performance Data):

Algorithm performance was tested using clinical data. The Cardiac Output accuracy of the modified algorithm testing was performed via retrospective analysis of clinical data from multiple independent datasets, comprised of data from patients over the age of 18 years. The results establish that the modification did not adversely affect the safety and effectiveness of the subject device. All testing passed without exception.

Software Verification

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". This verification included software design, development, and traceability. There were no changes to function, operation, or parameters monitored. Same methods, protocols,

and acceptance criteria as the predicate device (K201446) were used to evaluate the modification. All tests passed.

System Verification (Non-clinical Performance):

System verification activities confirmed that the modification to the device did not adversely affect the safety and effectiveness of the subject device, and the change in the algorithm was integrated without any concern and all integration passed with no exceptions. The same methods, protocols, and acceptance criteria as the predicate device (K201446) were used to evaluate the modification. All tests passed.

Design, materials, energy source, user interface, measurement principle, and all performance specifications of the modified HemoSphere ClearSight Module remain unchanged.

Conclusions

The clinical data demonstrate that the safety and effectiveness profile of the subject device is substantially equivalent to the predicate device. The technological characteristics of the subject and predicate devices are identical. The nonclinical and clinical tests demonstrate that the HemoSphere Advanced Monitoring Platform has successfully passed functional and performance testing, including software verification and validation, algorithm, validation and bench studies. The testing performed demonstrates that the HemoSphere Advanced Monitoring Platform with the subject modification of the HemoSphere ClearSight Module is substantially equivalent to the legally marketed predicate device.