June 16, 2021

Edwards Lifesciences, LLC
Varad Raghuwanshi
Sr. Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K201446
Trade/Device Name: HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ, MUD, DXN, DSB

Dear Varad Raghuwanshi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 1, 2020. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LT Stephen Browning, OHT2: Office of Cardiovascular Devices, 240-402-5241, Stephen.Browning@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

for LT 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

October 1, 2020

Edwards Lifesiences, LLC
Varad Raghuwanshi
Sr. Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K201446
Trade/Device Name: HemoSphere Advanced Monitoring Platform
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ, MUD, DXN, DSB
Dated: May 29, 2020
Received: June 1, 2020

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 -S5

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201446

Device Name
HemoSphere Advanced Monitoring Platform

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 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.

HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module

Traditional 510(k) – HemoSphere Advanced Monitoring Platform

The noninvasive 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 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 noninvasive 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 noninvasively 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.

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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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
Fax: (949) 809-2972

Date Prepared:
May 29, 2020

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 (*subjec*t)

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

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, K190205 (*cleared August 29, 2019*).
Additional Predicate Devices:	EV1000 Clinical Platform Non-Invasive NI and ClearSight™ Finger Cuffs or ClearSight™ System K160552 (*cleared June 1, 2016)* utilized for the ClearSight Module (*Non-invasive*) parameters. ClearSight finger cuff K190130 (*cleared June 21, 2019*) utilized for the ClearSight finger cuff used with ClearSight Module EV1000 Clinical Platform Non-Invasive NI and ClearSight™ Finger Cuffs or ClearSight™ System K182245 (*cleared November 30, 2018)* utilized for the Heart Reference Sensor FORE-SIGHT ELITE Module (smart cable) (K180003, cleared May 10, 2018) for tissue oximetry. Nexfin Model 2 (*cleared K122381 on April 22, 2013*) utilized as a reference predicate for the ClearSight workflow option.

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), FORE-SIGHT ELITE Tissue Oximeter Module (K180003, May 10, 2018), and the *subject* HemoSphere ClearSight Module. The *subject* HemoSphere ClearSight module is a non-invasive subsystem module intended to continuously and noninvasively measure blood

pressure and associated hemodynamic parameters. HemoSphere ClearSight module is intended to provide ClearSight functionality (Non-Invasive) previously cleared in EV1000 Clinical Platform NI (K160552 June 1, 2017) to the HemoSphere Advanced Monitoring Platform. It provides power, communications, air and an interface to connect with currently cleared and commercially available Edwards Lifesciences ClearSight System (K160552 June 1, 2016) which includes ClearSight finger cuffs (K160552 June 1, 2016 and K190130 June 21, 2019), Pressure Controller/Wrist Unit (K160552 June 1, 2016), Heart Reference Sensor (K182245 Nov 30, 2018), and the HemoSphere Advanced Monitor (K190205 August 29, 2019).

V. Indications for Use:

Note: The indication for Use statements are identical for all the previously cleared technologies (K190205 cleared August 29, 2019). with the exception of the addition of indication for subject HemoSphere ClearSight Module.

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 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.

HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module

The noninvasive 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 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

Note: The ClearSight indication is identical to the Predicate K160552 (Cleared June 1, 2016) with the exception of the addition of the HemoSphere Advanced Monitoring Platform.

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 noninvasive 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 noninvasively 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: 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			

sCO	STAT cardiac output	HemoSphere Swan-Ganz Module	Adult only	Operating Room, Intensive Care Unit, Emergency Room
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	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, StO_2, 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 existing HemoSphere Advanced Monitoring Platform which is the primary predicate for this submission consists of:

- HemoSphere Advanced Monitor
- HemoSphere Swan-Ganz Module
- HemoSphere Oximetry Cable
- HemoSphere Pressure Cable
- HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module
- Acumen Hypotension Prediction Index (use with FloTrac only)

The subject and predicate devices are based on the following same technological elements:

- Platform: The subject device uses the same platform as the Predicate (K190205 *cleared August 29, 2019*).

- Non-Invasive technology: The subject and Predicate (K160552 June 1, 2016) are Noninvasive blood pressure measurement systems and use the same method of measurement.

- Accessories/Components: The subject and the Predicate (K160552 June 1, 2016) device both use previously cleared Pressure controller, Heart Reference Sensor and ClearSight Cuffs for measurement of non-invasive parameters.

The following technological differences exist between the subject and predicate devices:

- Algorithm update: An updated optional continuous cardiac output algorithm has been incorporated into the HemoSphere Advanced Monitoring Platform. This algorithm provides the option for a more responsive Continuous Cardiac Output (averaged 20 seconds) parameter as compared to that from the existing algorithm (average of 3 to 7 minutes). The new Algorithm uses the same SwanGanz Module and Pressure Cable to provide already available cardiac output parameters as the predicate K190205 August 29, 2019.

- Algorithm update: For the key blood pressure (Noninvasive) parameters (MAP, SYS, DIA and PR) the algorithm has been changed to the existing algorithm used by HemoSphere Advanced Monitoring Platform (K190205 cleared August 29, 2019) to compute hemodynamic parameters (CO, CVP. MAP, DIA, MPAP, SV, SYS) when used with HemoSphere Pressure Cable (minimally invasive).

- Algorithm update: The FORE-SIGHT ELITE Tissue Oximeter Module algorithm for determining StO2 was updated to make more robust to better handle sensor disruption scenarios caused by user or environmental factors and made more dynamic for pediatric applications by increasing StO2 responsiveness. There are no new features with this algorithm update, and the device has comparable clinical accuracy when compared to the predicate device.

The purpose of this 510(k) submission is to add the following additional new features and modifications to the HemoSphere Advanced Monitoring Platform (*K190205, cleared August 29, 2019*):

Addition of the ClearSight™ (Non-Invasive) functionality to the HemoSphere Advanced Monitoring Platform (K190205, previously cleared August 29, 2019):

- HemoSphere ClearSight Module (HEMCSM10): A new sub-system module; ClearSight Module *(subject of this 510(k) submission)* is being added to the HemoSphere Advanced Monitoring Platform (*K190205, previously cleared August 29, 2019.*

- ClearSight Calibration feature (Optional feature): ClearSight Calibration provides an additional option to the user to manually calibrate blood pressure (BP) to an external reference.

- ClearSight workflow options*:* Allows the user flexibility to choose the mode of monitoring based on the patient's position throughout the monitoring session.

❖ **Modifications to existing elements of the HemoSphere Advanced Monitoring Platform (previously cleared in K190205, August 29, 2019):**

- Graphical User Interface Modifications: The graphical user interface (GUI) is being updated to include additional screens specifically for the non-invasive (or ClearSight™) blood pressure and hemodynamic parameters.

- Fluid Responsiveness Test for ClearSight: This feature is currently cleared for the minimally invasive (FloTrac) modes (*K190205, cleared August 29, 2019*). This same feature is now being made available for non-invasive ClearSight mode.

- Cybersecurity Updates: Cybersecurity enhancements have been made to the HemoSphere Advanced Monitoring Platform toaddress Cybersecurity risks.

- New Continuous Cardiac Output Algorithm: An updated cardiac algorithm (FastCCO) has been implemented for continuous cardiac output. This algorithmprovides the option for a more responsive Continuous Cardiac Output parameter as compared to the existing algorithm cleared in K163381 on April 14, 2017.

- FORESIGHT ELITE Tissue Oximeter Module Algorithm update: The FORE-SIGHT ELITE Tissue Oximeter Module algorithm for determining StO_2 was updated to make more robust to better handle sensor disruption scenarios caused by user or environmental factors and made more dynamic for pediatric applications by increasing StO2 responsiveness. There are no new features with this algorithm update, and the device has comparable clinical accuracy when compared to the predicate device.

❖ **Modifications to the Labeling of HemoSphere Advanced Monitoring Platform (previously cleared in K190205, August 29, 2019):**

- The HemoSphere Advanced Monitoring Platform Operator's Manual (Cleared in K190205 August 29, 2019) is being updated to include and address the additional and modified features that are the subject of this subject 510(k) premarket notification.

- The ClearSight™ Finger Cuffs (*Cleared in K160552 June 1, 2016 and K190130 June 21, 2019*) indications for use are being updated to add the HemoSphere Advanced

monitoring Platform to the indications for use as part of this subject 510(k). No other changes are occurring to the ClearSight Finger Cuffs.

- The Pressure Controller/Wrist Unit (*Cleared in K160552 June 1, 2016*) indications for use are being updated to add the HemoSphere Advanced monitoring Platform to the indications for use as part of this subject 510(k). No other changes are occurring to the Pressure Controller/Wrist Unit.

- The Heart Reference Sensor (*K182245 cleared November 30, 2018*) indications for use are being updated to add the HemoSphere Advanced monitoring Platform to the indications for use as part of this subject 510(k). No other changes are occurring to the Heart Reference Sensor.

Performance Data:

The following verification activities were performed in support of a substantial equivalence determination for the modifications being made as part of this submission.

Usability Study

Usability study was conducted per FDA's guidance document "*Applying Human Factors and Usability Engineering to Medical Devices*" to investigates primary operating functions and critical tasks of the system for any usability issues regarding HemoSphere Advanced Monitoring Platform that may lead to patient or user harm.

The usability study demonstrated that the intended users can perform primary operating functions and critical tasks of the system without any usability issues that may lead to patient or user harm.

System Verification (Non-Clinical Performance):

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.

Measured and derived parameters 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)

Electrical safety and EMC testing were conducted on the subject HemoSphere Advanced Monitoring Platform, consisting of the HemoSphere Monitor, the ClearSight Module, Pressure Controller, Heart Reference Sensor and finger cuff. The system complies with the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366-1, IEC 60601-2-34, IEC 60601-2-57, IEC 60601-2-49 and IEC 80601-2-49. All tests passed.

Wireless Coexistence Testing

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

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". Software on each of the individual modules was tested at a sub-system level to ensure the safety of the device. All tests passed.

Conclusions

The technological characteristics of the predicates and subject device are identical. The HemoSphere Advanced Monitoring Platform has successfully passed functional and performance testing, including software verification and validation, and bench studies. The test performed to demonstrate that the HemoSphere Advanced Monitoring Platform including the subject new features for the HemoSphere ClearSight Module and modified features for the platform is substantially equivalent to the legally marketed predicates.