November 7, 2022

Edwards Lifeciences, LLC
Michelle Ducca
Manager, Regulatory Affairs
1 Edwards Way
Irvine, California 92614

Re: K223127
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, QMS, FLL
Dated: September 30, 2022
Received: October 3, 2022

Dear Michelle Ducca:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K22XXXX

Device Name
HemoSphere Advanced Monitoring Platform

Indications for Use *(Describe)*

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. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. 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 or 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 Acumen Assisted Fluid Management Feature and Acumen IQ Sensor:
The Acumen Assisted Fluid Management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy.

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Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

HemoSphere Advanced Monitor with HemoSphere Technology Module and ForeSight Oximeter Cable
The noninvasive ForeSight Oximeter Cable 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 ForeSight Oximeter Cable is also intended to monitor relative changes of total hemoglobin of blood under the sensors. The ForeSight Oximeter Cable is intended to allow for the display of StO2 and relative change in total hemoglobin on the HemoSphere advanced monitor.

- When used with large sensors, the ForeSight Oximeter Cable is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with medium sensors, the ForeSight Oximeter Cable is indicated for use on pediatric subjects ≥3 kg.
- When used with small sensors, the ForeSight Oximeter Cable 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.

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

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: Michelle Ducca
Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
michelle_ducca@edwards.com
Telephone: (949) 250-4113

Date Prepared: September 30, 2022

II. Device Information:

Platform Name HemoSphere Advanced Monitoring Platform

Trade Name:
HemoSphere Advanced Monitor
HemoSphere Swan-Ganz Module
HemoSphere Oximetry Cable
HemoSphere Pressure Cable
HemoSphere Technology Module
HemoSphere ForeSight Oximeter Cable (Subject)
HemoSphere ClearSight Module
Acumen Hypotension Prediction Index (HPI) for Minimally Invasive and Non-Invasive technology
Viewfinder Remote (for non-invasive parameters)

Common Name: Cardiac Output/Oximetry/Ejection Fraction Computer

Classification Name for HemoSphere Monitor and Accessories:	Programmable Diagnostic Computer	21 CFR 870.1425
	Fiberoptic Oximeter Catheter	21 CFR 870.1230
	Adjunctive Predictive Cardiovascular Indicator	21 CFR 870.2210
	Oximeter, Tissue Saturation (Non-Invasive)	21 CFR 870.2700
	System, Measurement, Blood-Pressure, Non-Invasive	21 CFR 870.1130
	Plethysmograph, Impedance	21 CFR 870.2770

Product Code for HemoSphere Monitor and Accessories:	DQK, Class II DQE, Class II QAQ, Class II MUD, Class II DXN, Class II DSB, Class II

III. Predicate Device

Primary Predicate: HemoSphere Advanced Monitoring Platform, manufactured by Edwards Lifesciences, K213682 cleared June 22, 2022, is being utilized for substantial equivalence to the device modularity, basic device functionality, graphical user interface (GUI), and same existing StO_2 algorithm specifications. The subject device contains the same indications and intended use as the predicate device.

Additional Predicate: Fore-Sight Elite Module Tissue Oximeter, manufactured by Casmed Inc. (now part of Edwards Lifesciences), K143675 cleared April 10, 2015, is being utilized for substantial equivalence to the StO_2 algorithm. This predicate contains the original StO_2 algorithm for cerebral and somatic locations using all sensor sizes. It has the same principle of operation and similar intended and indications for use and performance as the subject device.

IV. Device Description:

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.

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 Oximeter Module (K190205 August 29, 2019), **HemoSphere ForeSight Oximeter Cable (K213682 cleared June 22, 2022)**, and the HemoSphere ClearSight Module (K203687 cleared May 28, 2021).

V. Indications for Use:

Indications for Use:

Note: *There is no change to the Indication for Use statements from what was previously cleared in K213682 on June 22, 2022*

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. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. 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 or 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 Acumen Assisted Fluid Management Feature and Acumen IQ Sensor:
The Acumen Assisted Fluid Management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

HemoSphere Advanced Monitor with HemoSphere Technology Module and ForeSight Oximeter Cable
The noninvasive ForeSight Oximeter Cable 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 ForeSight Oximeter Cable is also intended to monitor relative changes of total hemoglobin of blood under the sensors. The ForeSight Oximeter Cable is intended to allow for the display of StO_2 and relative change in total hemoglobin on the HemoSphere advanced monitor.

- When used with large sensors, the ForeSight Oximeter Cable is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with medium sensors, the ForeSight Oximeter Cable is indicated for use on pediatric subjects ≥3 kg.
- When used with small sensors, the ForeSight Oximeter Cable 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.

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

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 of the HemoSphere Advanced Monitor:

Note: *There is no change to the Intended Use from what was cleared in K213682 on June 22, 2022*

Intended Use- HemoSphere Advanced Monitoring Platform:
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 Viewfinder Remote mobile application can be used for supplemental near real-time remote display of monitored hemodynamic parameter data as well as Faults, Alerts and Notifications generated by the HemoSphere Advanced Monitoring Platform.

The HemoSphere Advanced Monitoring Platform is intended for use with compatible Edwards Swan-Ganz and Oximetry Catheters, FloTrac sensors, Acumen IQ sensors, TruWave DPT sensors, ForeSight sensors, and ClearSight/Acumen IQ finger cuffs.

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			
BT	pulmonary artery blood temperature			
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
SvO_2	Mixed Venous Oxygen Saturation	HemoSphere Oximetry Cable	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
$ScvO_2$	Central Venous Oxygen Saturation			

A comprehensive list of additional parameters that are available for adult and pediatric patient populations on the HemoSphere Advanced Monitor and a connected HemoSphere Swan-Ganz Module 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 and Pediatric	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 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 Arteria[l] Pressure			
PPV	pulse pressure variation[1]			
PRART	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_{ART}	Systemic Arterial Systolic Blood Pressure			
SYS_{PAP}	Pulmonary Artery Systolic Blood Pressure			
HPI	Acumen Hypotension Prediction Index[2]			
[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 list of Acumen Assisted Fluid Management (AFM) outputs available for surgical patients ≥18 years of age while monitoring with the HemoSphere Advanced Monitor and a connected HemoSphere pressure cable are as listed below:

AFM outputs	Sub-System Module Used	Patient Population	Hospital Environment
Fluid Bolus Suggested	HemoSphere Pressure Cable	≥18 years of age only	Operating Room
Test Bolus Suggested			
Fluid Not Suggested			
Suggestions Suspended			
Bolus in Progress…			
Bolus Complete			
Bolus Complete; Analyzing Hemodynamic Response			
Tracked Case Vol.			
AFM outputs are available when using an Acumen IQ sensor and if the AFM 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 pressure cable are 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			

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere Technology Module, and ForeSight Oximeter Cable are listed below.

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment

StO_2	Absolute regional hemoglobin oxygen saturation of blood under the sensors	ForeSight Oximeter Cable and HemoSphere Technology Module	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
ΔctHb	Relative change in Total Hemoglobin			

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	HemoSphereClearSight Module	Adult only	Operating Room, Intensive Care Unit, EmergencyRoom
DIA	Noninvasive arterial diastolic bloodpressure			
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			
dP/dt	Maximal slope of the arterialpressure upstroke[1]			
Ea_{dyn}	Dynamic Arterial Elastance[1]			
HPI	Acumen Hypotension PredictionIndex[1]			Operating Room only
[1]HPI parameters are available when using an Acumen IQ cuff and if the HPI feature is activated. *Note: CO/CI and SV/SVI are measured using a reconstructed brachial arterial waveform. All other monitored parameters use a reconstructed radial arterial waveform. SVR/SVRI are derived from CO/CI and MAP along with an entered or monitored CVP value.*				

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	Adult only	Operating Room,
DO_2I	Oxygen Delivery Indexed			
VO_2	Oxygen Consumption			

VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored	HemoSphere Oximetry Cable		Intensive Care Unit
VO_2I	Oxygen Consumption Index			
VO_2Ie	Estimated Oxygen Consumption Index when $ScvO_2$ is being monitored			

Intended Use of Viewfinder Remote:
Viewfinder Remote is a mobile application, which provides supplemental remote near real-time display of hemodynamic data measured by a connected HemoSphere advanced monitoring platform. Viewfinder Remote allows clinicians to view continuous monitoring data and alarms/alerts remotely for multiple patients. All displayed data is generated by connected HemoSphere advanced monitoring platforms, and not by Viewfinder Remote. Viewfinder Remote is intended for use by clinicians as a supportive visual aid, and not as a replacement for in-person patient monitoring with connected HemoSphere advanced monitoring platforms.

VI. Comparison of Technological Characteristics with the Predicate Devices:

The intended use, indications for use, labeling, instructions, and technological characteristics of the modified device remain unchanged between the subject and the predicate devices.

The following section provides a summary of the modification.

The purpose of this 510(k) submission is to introduce a modification to the HemoSphere ForeSight Oximeter Cable (model HEMFSM10) as part of the HemoSphere Advanced Monitoring Platform (cleared in K213682 on June 22, 2022):

- Modification to the existing StO_2 algorithm of the HemoSphere ForeSight Oximeter Cable (model HEMFSM10)

  The existing HemoSphere ForeSight Oximeter cable, which includes the StO_2 algorithm to measure tissue oxygen saturation, has been updated to bring the algorithm back to the existing specifications for specific adult somatic (arm and leg) locations using the ForeSight large sensor.

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.

Algorithm Verification:
Algorithm performance was tested using the same method and criteria as previously used in the predicate device. The results establish that the

modification did not adversely affect the safety and effectiveness of the subject device. All testing passed without exception.

System Verification
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. All integration passed with no exceptions The same methods, protocols and acceptance criteria as the predicate device (K213682) 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 ForeSight Oximeter cable remain unchanged.

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* (issued May 11, 2005). This verification included software design, development and traceability. There were no changes to the function, operation or parameters monitored. The same methods, protocols and acceptance criteria as the predicate device (K213682) were used to evaluate the modification. All tests passed.

Conclusions

Overall Conclusion:
The technological characteristics of the subject and predicate devices are identical. The HemoSphere Advanced Monitoring platform has successfully passed functional and performance testing, including software verification, algorithm and system test. The conducted testing demonstrates that the modified software algorithm did not adversely affect the safety and effectiveness of the subject device and is substantially equivalent to the predicate device.