June 22, 2022

Edwards Lifesciences, LLC
Manthan Damani
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K213682
Trade/Device Name: HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere ClearSight Module, HemoSphere Technology Module, HemoSphere ForeSight Oximeter Cable, Acumen Hypotension Prediction Index Feature, Acumen Assisted Fluid Management Feature, Viewfinder Remote
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: November 19, 2021
Received: November 22, 2021

Dear Manthan Damani:

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,

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)*

K213682

Device Name

HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere ClearSight Module, HemoSphere Technology Module, HemoSphere ForeSight Oximeter Cable, Acumen Hypotension Prediction Index Feature, Acumen Assisted Fluid Management Feature, Viewfinder Remote

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. 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 Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

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

HemoSphere Advanced Monitor with HemoSphere Oximetry Cable:

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

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

HemoSphere Advanced Monitor with HemoSphere Pressure Cable:

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

The Edwards 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 Acumen 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 non-invasive 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 on the HemoSphere advanced monitor.

- When used with large sensor, 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 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

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

Establishment Registration Number: 2015691

Contact Person: Manthan Damani
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
manthan_damani@edwards.com
Telephone: (949) 250-7853

Date: June 22, 2022

Platform Name HemoSphere Advanced Monitoring Platform

Trade Name:
HemoSphere Advanced Monitor
HemoSphere Swan-Ganz Module
HemoSphere Oximetry Cable
HemoSphere Pressure Cable
HemoSphere Technology Module *(subject)*
HemoSphere ForeSight Oximeter Cable *(subject)*
HemoSphere ClearSight Module
Acumen Hypotension Prediction Index software feature *(subject)*
Acumen Assisted Fluid Management software feature *(subject)*
Viewfinder Remote *(subject)*

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
Adjunctive Open Loop Fluid Therapy Recommender	21 CFR 870.5600
Thermometer, Electronic, Clinical	21 CFR 880.2910

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 QMS, Class II FLL, Class II
Primary Predicate Device for HemoSphere Monitor and Accessories:	HemoSphere Advanced Monitoring Platform, manufactured by Edwards Lifesciences, K203687 cleared May 28, 2021, is being utilized for substantial equivalence to the device modularity, basic device functionality, graphical user interface (GUI) used, core predictive algorithm for the Acumen Hypotension Prediction Index (HPI) feature, and cybersecurity features. The indications for use are also similar to the subject device.
Secondary Predicate Devices for HemoSphere Monitor and Accessories:	FORE-SIGHT ELITE Tissue Oximeter Module (*K190270, cleared October 21, 2019*), manufactured by Edwards Lifesciences, is being utilized for substantial equivalence to the tissue hemoglobin feature and indications for use. Acumen Assisted Fluid Management (AFM) feature on EV1000A Clinical Platform (*DEN190029, granted November 13, 2020*), manufactured by Edwards Lifesciences, is being utilized for substantial equivalence to the Acumen Assisted Fluid Management (AFM) software feature and indications for use. HemoSphere Advanced Monitoring Platform (*K211465, cleared July 08, 2021*), manufactured by Edwards Lifesciences, is being utilized for substantial equivalence to the connectivity features of the HemoSphere Advanced monitor to allow it to connect to the Viewfinder Remote mobile application as well as for the Viewfinder Remote application itself.
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, subject of this submission, consists of the HemoSphere Advanced Monitor that provides a means to interact with and visualize hemodynamic and volumetric data on the monitor screen and its 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 Technology Module (previously referred to as “Tissue Oximetry Module”; K190205 cleared, August 29, 2019),

HemoSphere ForeSight Module (K180003, May 10, 2018), and the HemoSphere ClearSight Module (K203687 cleared, May 28, 2021). The HemoSphere Advanced Monitor also has wired and wireless capabilities which was originally used only for connecting to a Hospital Information System (HIS) for data charting purposes. This capability is now used to allow it to stream continuously monitored data to the Viewfinder Remote, a mobile device-based application, for remote viewing the information (K211465 cleared July 8, 2021). The remotely transmitted data from the patient monitoring sessions include all hemodynamic parameter data and the associated physiological alarm notifications, historical trend data, and parameter waveform data.

A high-level overview of the new features and modifications that have been implemented as part of this subject submission are listed below:

- ***Addition of new features, algorithm, and/or technology to the HemoSphere Platform:***
    - Tissue Hemoglobin
        - The updated ForeSight Oximeter Cable (previously referred to as "FORE-SIGHT ELITE Oximeter Module/FSM") with the Tissue Hemoglobin algorithm (K190270 cleared October 21, 2019) has been incorporated into the HemoSphere Monitoring Platform. The tissue hemoglobin parameter includes relative changes in oxygenated and deoxygenated hemoglobin concentrations for assessment of oxygenation changes as well as their sum total hemoglobin concentration, under the sensor when used with a compatible host monitor. As such, the indications for use and intended use of the existing HemoSphere Advanced Monitor have been expanded to include the ability to measure relative change in total hemoglobin. Additionally, since the HemoSphere Advanced Monitor will act as the host monitor, the graphical user interface (GUI) of the Monitor is being updated to allow display of the hemoglobin parameter.

    - Assisted Fluid Management software feature:
        - The Edwards' Acumen™ Assisted Fluid Management (AFM) software feature (DEN190029 granted on November 13, 2020) has been incorporated into the HemoSphere Advanced Monitoring Platform to recognize patterns of fluid responsiveness (i.e., hemodynamic data and past responses to fluid) and recommend when fluid administration is expected to improve the patient's hemodynamic state. This AFM software feature (AFM algorithm + AFM GUI) is now being incorporated as part of the HemoSphere Advanced Monitor. No modifications have been made to the previously granted AFM algorithm.

- ***Updates to existing features, algorithm, and/or technology to the HemoSphere Platform:***
  - HPI Smart Alerts and Smart Trends
    - The Acumen Hypotension Prediction Index (HPI) algorithm defines hypotensive events as mean arterial pressure (MAP) < 65 mmHg for at least one minute in duration. The software triggers an alert screen whenever the HPI parameter value is greater than 85 for two consecutive readings. From the alert screen, the user has the option to go to a secondary screen, where additional data related to alert can be viewed.

      Modifications have been made to the HPI alert popup and HPI secondary screen. The appearance and behavior of the HPI alert popup (referred to as a Smart Alert popup) has been modified to display the physiological mechanisms of preload, contractility, and afterload that may have changed in accordance with user-defined settings. The HPI secondary screen options also now include a new Smart Trends screen that displays values and trends for user-defined parameters associated with preload, contractility, and afterload when they have reached the user-defined targets. The Smart Settings menu allows clinician to select parameters to be monitored for each physiological mechanism (preload, contractility, afterload), and customize when the mechanism is triggered based on the percent change threshold over a pre-set time interval. There are no changes to the core HPI algorithm, the behavior of the HPI parameter display, nor the indications for use and intended use of the HPI parameter due to this Smart Trends/ Smart Alerts modification.

  - Connectivity feature
    - As part of its connectivity development program, Edwards had modified the HemoSphere Advanced Monitor (K211465 cleared July 8,2021) to allow it to stream (wired or wireless) continuously monitored non-invasive hemodynamic data to the Viewfinder Remote, a mobile device-based application, for remote viewing the information.

      Modifications have been made to the connectivity feature on HemoSphere Advanced Monitoring Platform to also allow the remote display of minimally invasive and invasive hemodynamic data on the physicians/clinicians mobile/handheld devices such as cell phone using Viewfinder Remote application. Additional connectivity feature modifications include workflow-based updates to the HemoSphere monitor to support the functionality of remote viewing, including the ability to end a session, additional metadata support, multiple setup wizards for initial configuration, as well as remote software and cybersecurity patch updates.

- Cybersecurity updates
  - Cybersecurity updates on HemoSphere Monitor include Windows 10 IoT and cybersecurity tools, OS and App level hardening, and dedicated security logs.

- Miscellaneous Updates:
  - ForeSight Sensor surface temperature detection
  - Non-Pulsatile Mode
  - CASMED IFMOut/EMR protocol integration
  - Status Screen Updates
  - Default CVP Values
  - Nomenclature changes due to rebranding

- Viewfinder Remote Application updates
  - The intended use of the Viewfinder Remote mobile application, which is an accessory to the HemoSphere Monitor (K211465, cleared July 08, 2021), has been expanded to allow for remote display of all existing hemodynamic data from the HemoSphere monitor including minimally invasive and invasive parameters on the physicians/clinicians mobile/handheld devices such as cell phone when using Viewfinder Remote application (previously only allowed display of the non-invasive parameters). Please Note: The AFM feature is not offered or displayed on Viewfinder Remote.

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. 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.

Intended Use of the HemoSphere Advanced Monitor:

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	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			
dP/dt	Maximal slope of the arterial pressure upstroke[1]			
Ea_{dyn}	Dynamic Arterial Elastance[1]			
HPI	Acumen Hypotension Prediction Index[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 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			

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.

Comparison of Technological Characteristics with Predicate Devices:

The existing HemoSphere Advanced Monitoring Platform, K203687 (cleared May 28, 2021) consists of:

- HemoSphere Advanced Monitor
- HemoSphere Swan-Ganz Module
- HemoSphere Oximetry Cable
- HemoSphere Pressure Cable
- HemoSphere Technology Module (previously known as "Tissue Oximetry Module")
- HemoSphere ForeSight Oximeter Cable (previously known as "FORE-SIGHT ELITE Tissue Oximeter Module")
- HemoSphere ClearSight Module
- Acumen Hypotension Prediction Index (HPI) for Minimally Invasive and Non-Invasive technology
- Viewfinder Remote Mobile Application (for non-invasive parameters)

Per the FDA Guidance, *Deciding When to Submit a 510(k) for a Change to an Existing Device* (October 25, 2017), the modifications made to the HemoSphere Advanced Monitoring Platform as part of this submission are considered as technology, engineering, and performance changes. A summary of the new and modified technological characteristics of the subject device along with a reference to the predicate device(s) for those characteristics are provided below:

New/Modified Feature or Technology	Predicate Device Chosen with Justification
HemoSphere Advanced Monitoring Platform	***HemoSphere Advanced Monitoring Platform (K203687, cleared May 28, 2021)*** This is the base platform to which the new features, technology additions or modifications (inclusive of miscellaneous GUI/ functionality modifications) are being made and has similar intended use and indications and hence is the ***Primary Predicate.***

Tissue Hemoglobin Software Feature and Parameters	***FORE-SIGHT ELITE Tissue Oximeter Module (K190270 cleared October 21, 2019)*** This device (smart cable) was chosen as a secondary predicate for the new indication on the HemoSphere platform related to the hemoglobin parameters (oxygenated hemoglobin, deoxygenated hemoglobin, and their summation total hemoglobin, of blood under the sensors). The algorithm for this parameter is directly being ported over from what was cleared for the FORE-SIGHT ELITE Tissue Oximeter Module (also now referred to as HemoSphere ForeSight Oximeter Cable (FSOC) as part of rebranding that is occurring). There are GUI modifications being made to integrate it with the HemoSphere Advanced Monitoring Platform.
Assisted Fluid Management and Acumen AFM Cable	***Acumen Assisted Fluid Management (AFM) Software Feature (DEN190029 granted November 13, 2020)*** This software feature was chosen as the secondary predicate since the Assisted Fluid Management algorithm and feature, as granted in this DeNovo will be used on the HemoSphere Advanced Monitor.
HPI Smart Trends and Alerts	***HemoSphere Advanced Monitoring Platform (K203687 cleared May 28, 2021)*** This device was chosen as the predicate since it is the base HemoSphere platform for the HPI feature to which modifications are being made. There are no changes to the core HPI algorithm, the behavior of the HPI parameter display, nor the indications for use and intended use of the HPI parameter due to this Smart Trends/ Smart Alerts modification.
Connectivity Solutions	***HemoSphere Advanced Monitoring Platform (K211465 cleared July 8, 2021)*** This device was chosen as the predicate for the connectivity features that allow the HemoSphere Advanced Monitor to connect to the Viewfinder Remote mobile application. Modifications have been made to the connectivity feature on HemoSphere Advanced Monitor to enable remote software and cybersecurity patch updates and also allow the remote display of minimally invasive and invasive hemodynamic data when connected to the Viewfinder Remote mobile application.
Cybersecurity Modifications	***HemoSphere Advanced Monitoring Platform (K203687 cleared May 28, 2021)*** This device was chosen as the predicate since it is the base platform to which modifications are being made. There are no changes to the fundamental technology.
Viewfinder Remote	***HemoSphere Advanced Monitoring Platform (K211465 cleared July 8, 2021)*** This device is chosen as the predicate for Viewfinder Remote modifications. The Viewfinder Remote was originally cleared as an accessory to the HemoSphere Advanced Monitoring Platform for non-invasive parameters. Modifications have been made to allow remote display of minimally invasive and invasive hemodynamic data when connected to the HemoSphere Advanced Monitor.

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

- Platform: The subject device uses the same platform as the primary predicate (K203687, *cleared May 28, 2021*).
- Graphical User Interface: The subject device has the same overall Graphical User Interface (GUI) as the primary predicate (K203687, *cleared May 28, 2021*).

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

- Tissue Hemoglobin software feature: The updated ForeSight Oximeter Cable (previously referred to as "FORE-SIGHT ELITE Oximeter Module/FSM") with the Tissue Hemoglobin algorithm (K190270 cleared October 21, 2019) has been incorporated into the HemoSphere Monitoring Platform. The tissue hemoglobin parameter includes relative changes in total hemoglobin concentration under the sensor when used with the HemoSphere Advanced Monitor. The graphical user interface (GUI) of the HemoSphere Monitor has been updated to allow display of the hemoglobin parameter.
- Acumen™ Assisted Fluid Management (AFM) software feature: The Edwards' Acumen™ Assisted Fluid Management (AFM) software feature (DEN190029 *granted on November 13, 2020*) has been incorporated into the HemoSphere Advanced Monitoring Platform to recognize patterns of fluid responsiveness (i.e., hemodynamic data and past responses to fluid) and recommend when fluid administration is expected to improve the patient's hemodynamic state. This AFM software feature (AFM algorithm + AFM GUI) has now been incorporated as part of the HemoSphere Advanced Monitor. No modifications have been made to the previously granted AFM algorithm.
- HPI Smart Alerts and Smart Trends software feature: Modifications have been made to the HPI alert popup and HPI secondary screen. The appearance and behavior of the HPI alert popup (referred to as a Smart Alert popup) has been modified to display the physiological mechanisms of preload, contractility, and afterload that may have changed in accordance with user-defined settings. The HPI secondary screen options also now include a new Smart Trends screen that displays values and trends for user-defined parameters associated with preload, contractility, and afterload when they have reached the user-defined targets. There are no changes to the core HPI algorithm due to this Smart Trends/ Smart Alerts modification.

Performance Data (Bench and/or Clinical):

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

System Verification (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 features and design 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. End-to-end system verification was performed to ensure data integrity and accuracy from the Monitor to the Viewfinder Remote application. 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 Technology Module, HemoSphere ForeSight Oximeter Cable. The system complies with the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366, IEC 60601-2-34, IEC 60601-2-57, IEC 60601-2-49, and IEC 80601-2-49. All tests passed.

Wireless Coexistence Testing
ANSI C63.27/D1.0, bench and simulated environment testing were performed on the entire HemoSphere Advanced Monitoring Platform, including all sub-system modules and its interfacing analog inputs and outputs and the wirelessly connected Viewfinder Remote mobile application running on a mobile device. 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* (issued May 11, 2005). Software on each of the updated modules and algorithms were tested at a sub-system level to ensure the safety of the device. All tests passed.

Usability Study
Usability study was conducted per FDA's guidance document, *Applying Human Factors and Usability Engineering to Medical Devices* (issued February 3, 3016), to investigate 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 could perform primary operating functions and critical tasks of the system without any usability issues that may lead to patient or user harm.

Clinical Performance
No new clinical testing was performed in support of the subject 510(k).

Conclusions

Overall Conclusion:

The HemoSphere Advanced Monitoring Platform with the subject modifications has successfully passed functional and performance testing, including software verification and validation, algorithm, and bench studies. Completion of all performance 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 features and design did not adversely affect the safety and effectiveness of the subject device. The testing performed demonstrates that the HemoSphere Advanced Monitoring Platform with the subject modifications and expanded indications for use is substantially equivalent to its legally marketed predicates.