June 9, 2023

Edwards Lifesciences, LLC
Sara Pesian
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K223865
Trade/Device Name: HemoSphere Advanced Monitor, HemoSphere ClearSight Module, Acumen Assisted Fluid Management software feature with Acumen AFM Cable and Acumen IQ fluid meter, Pressure Controller, Heart Reference Sensor
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, QAQ, MUD, DXN, DSB
Dated: May 9, 2023
Received: May 10, 2023

Dear Sara Pesian:

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,

Robert T. Kazmierski -S

for

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

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K223865

Device Name
HemoSphere Advanced Monitoring Platform, Acumen Assisted Fluid Management software feature with Acumen AFM Cable and Acumen IQ fluid meter

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.

The Acumen Assisted Fluid management software feature may be used with the Acumen AFM Cable and Acumen IQ fluid meter.

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: Sara Pesian
Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
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Date: June 08, 2023

Platform Name: HemoSphere Advanced Monitoring Platform

Trade Name:
HemoSphere Advanced Monitor *(subject device)*
HemoSphere ClearSight Module *(subject device)*
Heart Reference Sensor *(subject device)*
Pressure Controller *(subject device)*
HemoSphere Swan-Ganz Module
HemoSphere Oximetry Cable
HemoSphere Pressure Cable
HemoSphere Technology Module
HemoSphere ForeSight Oximeter Cable
Acumen Hypotension Prediction Index software feature
Acumen Assisted Fluid Management software feature with Acumen AFM Cable and Acumen IQ fluid meter *(subject device)*
Viewfinder Remote

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	The 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) used, core predictive algorithm for the Assisted Fluid Management software feature, and cybersecurity features. The indications for use are also similar to the subject device.
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 (K213682 cleared, June 22, 2022), HemoSphere ForeSight Module (K213682, June 22, 2022), and the HemoSphere ClearSight Module (K203687 cleared, May 28, 2021). Additionally, the HemoSphere Advanced Monitoring Platform includes the Acumen Hypotension Prediction Index software feature (DEN160044 granted March 16, 2018) and the Acumen Assisted Fluid Management software feature (DEN190029 granted November 13, 2020). 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.

HemoSphere Advanced Monitoring platform as cleared in K213682 cleared June 22, 2022, is being modified as follows:

1) Acumen Assisted Fluid Management – Automated Fluid Tracking Mode:

The AFM software feature (AFM algorithm + AFM GUI), which informs clinicians of patient fluid responsiveness (K213682, cleared June 22, 2022), allows for manual fluid tracking, and resides on the HemoSphere Advanced Monitor.

The AFM software feature is being modified to allow for an automated fluid tracking mode as the default mode. Users can switch to the optional manual fluid tracking mode through the advanced settings menu. This automated fluid tracking mode for the AFM software feature is achieved via two components namely, the Acumen AFM Cable and the Acumen IQ fluid meter (both devices subject of this 510(k)). No modifications have been made to the previously cleared AFM algorithm. AFM GUI screens have been updated to account for the automated fluid tracking mode via the Acumen AFM cable and Acumen IQ fluid meter.

The Acumen AFM Cable is a reusable cable that connects the Acumen IQ fluid meter to the HemoSphere Advanced Monitoring Platform and converts the flow rate received from the Acumen IQ fluid meter to total volume for the HemoSphere monitor to be used by AFM software feature. No modifications have been made to the previously cleared AFM algorithm. AFM GUI screens have been updated to account for the automatic fluid tracking mode. The Acumen IQ fluid meter is a sterile, single use device that measures the flow of fluid delivered to a patient through the intravenous line to which it is connected.

When used together, the Acumen IQ fluid meter with the Acumen AFM Cable connected to a HemoSphere monitor, the fluid volume can be automatically tracked and displayed on the monitor as part of the AFM software feature screens.

2) Automatic Zeroing of the Heart Reference Sensor (HRS)

The ClearSight Module (CSM), initially cleared in K201446 on October 1, 2020, is a non-invasive monitoring platform that includes a Pressure Controller (PC2) that is worn on the wrist, a Heart Reference Sensor (HRS), and the ClearSight/Acumen IQ Finger Cuffs.

The Pressure Controller (also referred to as ‘Wrist unit’ or PC2) is connected to the patient via a wrist band. The Pressure Controller connects to the ClearSight Module (CSM) on one end and with the Heart Reference Sensor (HRS) and the finger cuff on the other. The connection to the CSM provides power and serial communication. The Pressure Controller is

designed to control the blood pressure measurement process and send the finger arterial pressure waveform to the CSM. The CSM software transforms the finger level blood pressure measurements into the conventional radial blood pressure.

In the predicate HemoSphere (K213682, cleared on June 22, 2022), as part of the ClearSight workflow, the user was required to zero the HRS prior to monitoring by aligning both ends of the HRS, the heart end and the finger end, and pressing the "0" button on the HemoSphere Graphical User Interface (GUI). After zeroing the HRS, the user is required to place both ends of the HRS in the appropriate location and then they can begin monitoring.

For the subject device, the Pressure Controller (PC2) firmware has been updated to include a mathematical model that automatically calculates the zero offset of the HRS based on the age of the specific HRS at the time of use. With the addition of the mathematical model, the user is no longer required to zero the HRS prior to start of monitoring since the system now has the zero-offset calculated. As such, the HemoSphere Advanced Monitor graphical user interface (GUI) was updated to remove the Zero HRS step as part of the Zero & Waveform screen and ClearSight setup.

The ClearSight Module firmware was also updated as part of support for the Automatic Zeroing of HRS feature. The firmware update included additional logging to support HRS calibration, bug fixes and updates to communication to the pressure controller to support display of proper HRS calibration information.

3) Patient Query

As cleared in K213682, when the user queried for patient information, all patient records that match the search criteria were sent to the HemoSphere platform (from the Viewfinder Hub) for the user to review. With this update, only 30 records are shared at a time between the Viewfinder Hub and HemoSphere monitor.

4) Miscellaneous Updates

Miscellaneous updates include:

- Bug fixes
- Cybersecurity updates
- Operator's manual updates
- Heart Reference Sensor Instructions for Use update

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.

The Acumen Assisted Fluid Management software feature may be used with the Acumen AFM Cable and Acumen IQ fluid meter.

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.

Indications for Use for the Acumen IQ Fluid Meter

The Acumen IQ fluid meter is indicated for surgical patients over 18 years of age to track the fluid being administered to the patient, when used with a compatible hemodynamic monitoring platform.

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, Acumen IQ fluid meter, 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 and Acumen AFM 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.			
Flow Rate			
Bolus Volume			
AFM outputs are available when using an Acumen IQ sensor and if the AFM feature is activated. Flow rate and Bolus Volume are visible when using automatic fluid tracking mode.			

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, EmergencyRoom
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 – Acumen IQ Fluid Meter

The Acumen IQ fluid meter is a sterile single use device that is intended to be used with the Acumen AFM Cable and AFM software feature to inform the user of the rate of flow. The device is intended to be used by qualified personnel or clinicians in a clinical setting for up to 24 hours.

Comparison to Predicate Device:

A summary comparison of the subject to predicate device is provided below:

Subject Feature/Technology	Predicate Device Chosen with Justification
HemoSphere Advanced Monitoring Platform	HemoSphere Advanced Monitoring Platform (K213682 cleared June 22, 2022) 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.***
Acumen Assisted Fluid Management feature on HemoSphere monitor with automated tracking via Acumen AFM cable and Acumen IQ fluid meter	HemoSphere advanced monitor with Acumen Assisted Fluid Management software feature with manual fluid tracking mode (K213682 cleared June 22, 2022). This software feature was chosen as the primary predicate since the Assisted Fluid Management algorithm and feature, as cleared in this submission will be used on the HemoSphere Advanced Monitor. An additional option is being added to the HemoSphere Advanced Monitor that allows the user to automatically track amount of fluid administered via two components, namely, the Acumen AFM Cable and Acumen IQ fluid meter.
Automatic Zero of Heart Reference Sensor	HemoSphere advanced monitor with HemoSphere ClearSight Module (K213682 cleared May 22, 2022) This device was chosen as the predicate since it allows zeroing of the Heart Reference Sensor prior to monitoring and is now being modified to automatically zero the HRS.
Patient Query	HemoSphere Advanced Monitoring Platform (K213682, cleared June 22, 2022) This device was chosen as the predicate since it is the base platform with the patient query feature to which modifications are being made. There are no changes to the fundamental technology.
Miscellaneous Updates (bug fixes, cybersecurity, labeling)	HemoSphere Advanced Monitoring Platform (K213682, cleared June 22, 2022) This device was chosen as the predicate since it is the base platform to which modifications (bug fixes and cybersecurity updates) are being made. There are no changes to the fundamental technology.

Performance Data (Bench and/or Clinical):

The following verification activities were performed in support of a substantial equivalence determination for the modifications made to the HemoSphere Advanced Monitoring Platform due to the modifications to the Acumen Assisted Fluid Management software feature, Automatic Zeroing of the Heart Reference Sensor, Patient Query, and Bug and cybersecurity updates and to ensure the safety and effectiveness of the new Acumen AFM Cable and Acumen IQ fluid meter components.

System Verification (Non-clinical performance)

Completion of all verification and validation activities demonstrated that the subject devices and software meet their predetermined design and performance specifications. Verification activities performed confirmed that the modifications made to the HemoSphere Advanced Monitoring Platform did not adversely affect the safety and effectiveness of the subject device. The Acumen AFM Cable when connected to Acumen IQ fluid meter were tested at a system level to verify the safety of these components. AFM outputs when the fluid meter mode was unlocked using the Acumen AFM Cable and the Acumen IQ fluid meter were tested using a bench simulation. 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, Acumen AFM Cable with Acumen IQ fluid meter. 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 ISO 81060-2. All tests passed.

Additionally, Electrical testing was performed on the Acumen IQ fluid meter's disposable board and the Acumen AFM Cable's reusable board to ensure they meet all their electrical requirements specification

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). The new advanced feature (AFM fluid meter mode) added to HemoSphere AFM Software was tested at a sub-system level to ensure the safety of the device. The Acumen AFM Cable and HemoSphere ClearSight Module firmware was tested 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 AFM fluid meter mode on 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.

Mechanical Testing
Mechanical testing was performed on the Acumen IQ fluid meter and the Acumen AFM Cable to ensure they meet all their mechanical requirements specification. All tests passed.

Sterilization Validation
The Acumen IQ fluid meter is provided sterile. As such, sterilization validation and shelf life of the device was performed in accordance with the Edwards Quality System and the applicable standards.

Packaging Testing
Acumen IQ fluid meter packaging configurations were validated in accordance with the requirements of ISO 11607-1: 2009/A1: 2014. Shipping simulation and conditioning tests were completed to demonstrate the sterile barrier produced under the worst-case parameters and distribution conditions maintain sterile barrier integrity. Packaging testing was also performed on the Acumen AFM Cable. All test passed.

Biocompatibility Testing
Since the Acumen IQ fluid meter is considered to have indirect contact with the patient, biocompatibility testing was performed in accordance with the requirements of ISO 10993-1: 2009 – *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process* and FDA guidance document: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (June 16, 2016).* All tests passed.

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

Conclusions

Overall Conclusion:
The Acumen AFM Software Feature on HemoSphere Advanced Monitoring Platform with the subject modifications has successfully passed functional and performance testing, including software verification and validation ,bench, and usability 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 subject modifications to the Acumen Assisted Fluid Management software feature with Acumen AFM Cable and Acumen IQ fluid meter, Automatic Zeroing of the Heart Reference Sensor, Patient Query, bug fixes and cybersecurity updates is substantially equivalent to its legally marketed predicate device.