October 31, 2023

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

Re: K232294
Trade/Device Name: HemoSphere Alta Advanced Monitoring Platform
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ, MUD, DXN, DSB, QMS, FLL, QNL
Dated: July 31, 2023
Received: August 1, 2023

Dear Varad Raghuwanshi:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K232294

Device Name
HemoSphere Alta Advanced Monitoring Platform

Indications for Use *(Describe)*
HemoSphere Alta Monitor with Swan-Ganz Technology

The HemoSphere Alta monitor when used with the HemoSphere Alta Swan-Ganz patient cable 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 in a hospital environment. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. 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 Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

The Global Hypoperfusion Index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm provides the risk of a global hypoperfusion event (defined as $SvO2 \leq 60\%$ for at least 1 minute) occurring in the next 10-15 minutes. The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter. The GHI algorithm is considered to provide additional information regarding the patient's predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions.

HemoSphere Alta monitor with HemoSphere Oximetry Cable

The HemoSphere Alta 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 Alta Monitor with HemoSphere Pressure Cable

The HemoSphere Alta 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 of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, Acumen IQ sensor, and TruWave DPT indications for use statements for information on target patient populations specific to the sensor/transducer 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.

When used in combination with the HemoSphere Pressure Cable connected to a compatible Swan-Ganz catheter, the Edward Lifesciences Right Ventricular Pressure (RVP) algorithm provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVP algorithm is indicated for critically ill patients over 18 years of age receiving advanced hemodynamic monitoring in the operating room (OR) and intensive care unit (ICU). The RVP algorithm 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 Right Ventricular Pressure (RVP) parameters.

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

HemoSphere Alta Monitor with 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 and relative change in total hemoglobin on the HemoSphere Alta 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 Alta Monitor with ClearSight Technology

The HemoSphere Alta when used with the 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 comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult.

The HemoSphere Alta monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. 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.

The Edwards Acumen Hypotension Prediction Index (HPI) 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 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 Alta 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.

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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Edwards

510(k) Summary – HemoSphere Alta Advanced Monitoring Platform

I. Submitter:

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

Establishment Registration Number: 2015691

Contact Person: Varad Raghuwanshi
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One Edwards Way
Irvine, CA 92614
Telephone: (949) 756-4502
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Date Prepared: July 28, 2023

II. Device Information:

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

Trade Name:
HemoSphere Alta Advanced Cardiac Monitor
HemoSphere Alta Advanced Smart Recovery Monitor
HemoSphere Alta All-on-One monitor
Acumen Hypotension Prediction Index software feature
Acumen Assisted Fluid Management software feature
Right Ventricular Pressure Feature
Global Hypoperfusion Index Feature
CCO Cable - HemoSphere Alta monitoring platform

Common Name: Programmable Diagnostic/Oximetry/Ejection Fraction/ Noninvasive blood pressure measurement computer/Adjunctive predictive Cardiovascular Indicator/Adjunctive Open Loop Fluid Therapy Recommender

Classification Name:

Programmable Diagnostic Computer	21 CFR 870.1425
Fiberoptic Oximeter Catheter	21 CFR 870.1230
Adjunctive Predictive Cardiovascular Indicator	21 CFR 870.2210
Oximeter, Tissue Saturation	21 CFR 870.2700

	Noninvasive blood pressure measurement system	21 CFR 870.1130
	Impedance plethysmograph	21 CFR 870.2770
	Thermometer, Electronic, Clinical	21 CFR 880.2910
	Adjunctive Open Loop Fluid Therapy Recommender	21 CFR 870.5600
	Medium-Term Adjunctive Predictive Cardiovascular Indicator	21 CFR 870.2210

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

III. Predicate Device

Primary Predicate Device:	HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K213682, cleared on June 22, 2022.
Additional Predicate Devices:	HemoSphere Advanced Monitoring Platform by Edwards Lifesciences, K221704 cleared on Nov 22, 2022, utilized for the Right Ventricular Pressure (RVP) parameter. Global Hypoperfusion Index (GHI) algorithm by Edwards Lifesciences K231038 cleared on July 26, 2023) utilized for the Global Hypoperfusion Index (GHI) parameter.

IV. Device Description

Device Description:	The HemoSphere Alta™ Advanced Monitoring Platform is Edwards' next-generation platform that provides a means to interact with and visualize hemodynamic and volumetric data on a screen. The HemoSphere Alta™ Monitoring Platform provides an improved user interface utilizing the existing Edwards technologies and algorithms commercially available in the HemoSphere Advanced Monitoring Platform.

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V. Indications for Use:

HemoSphere Alta Advanced Monitor with Swan-Ganz Technology

The HemoSphere Alta monitor when used with the HemoSphere Alta Swan-Ganz patient cable 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 in a hospital environment. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. 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 Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

The Global Hypoperfusion Index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm provides the risk of a global hypoperfusion event (defined as $SvO2 \leq 60\%$ for at least 1 minute) occurring in the next 10-15 minutes. The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter. The GHI algorithm is considered to provide additional information regarding the patient's predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions.

HemoSphere Alta monitor with HemoSphere Oximetry Cable

The HemoSphere Alta 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.

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HemoSphere Alta Advanced Monitor with HemoSphere Pressure Cable

The HemoSphere Alta 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 of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, Acumen IQ sensor, and TruWave DPT indications for use statements for information on target patient populations specific to the sensor/transducer 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.

When used in combination with the HemoSphere Pressure Cable connected to a compatible Swan-Ganz catheter, the Edward Lifesciences Right Ventricular Pressure (RVP) algorithm provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVP algorithm is indicated for critically ill patients over 18 years of age receiving advanced hemodynamic monitoring in the operating room (OR) and intensive care unit (ICU). The RVP algorithm 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 Right Ventricular Pressure (RVP) parameters.

HemoSphere Alta Advanced Monitor with Acumen Assisted Fluid Management Feature and Acumen IQ Sensor

The Acumen assisted fluid management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy.

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

HemoSphere Alta Advanced Monitor with 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 and relative change in total hemoglobin on the HemoSphere Alta 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.

HemoSphere Alta Advanced Monitor with ClearSight Technology

The HemoSphere Alta when used with the 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 comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere Alta monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters.

The Edwards Acumen Hypotension Prediction Index (HPI) 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 Acumen Hypotension Prediction Index (HPI) parameter.

Intended Use: The HemoSphere Alta Advanced Monitoring Platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

The HemoSphere Alta Advanced Monitoring Platform is intended for use with compatible Edwards Swan-Ganz and oximetry catheters, FloTrac sensors, Acumen IQ sensors, TruWave DPTs, ForeSight /ForeSight Jr sensors, and ClearSight/Acumen IQ finger cuffs.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta Advanced Monitor and a connected Swan-Ganz patient cable are listed below. Only iCO, iCI, iSVR, and iSVRI are available to the pediatric patient population.

Parameter	Description	Patient Population	Hospital Environment
CO	continuous cardiac output	Adult only	Operating Room, Intensive Care Unit, Emergency Room
sCO	STAT cardiac output		
CI	continuous cardiac index		
sCI	STAT cardiac index		
EDV	right ventricular end diastolic volume		
sEDV	STAT right ventricular end diastolic volume		
EDVI	right ventricular end diastolic volume index		
sEDVI	STAT right ventricular end diastolic volume index		
HR_{avg}	averaged heart rate		
LVSWI	left ventricular stroke work index		
PVR	pulmonary vascular resistance		
PVRI	pulmonary vascular resistance index		
RVEF	right ventricular ejection fraction		
sRVEF	STAT right ventricular ejection fraction		
RVSWI	right ventricular stroke work index		
SV	stroke volume		
SVI	stroke volume index		
SVR	systemic vascular resistance		
SVRI	systemic vascular resistance index		
iCO	intermittent cardiac output	Adult and Pediatric	
iCI	intermittent cardiac index		
iSVR	intermittent systemic vascular resistance		
iSVRI	intermittent systemic vascular resistance index		

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Alta Advanced Monitor and a connected HemoSphere oximetry cable are as listed below:

Parameter	Description	Patient Population	Hospital Environment
SvO2	Mixed Venous Oxygen Saturation	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
ScvO2	Central Venous Oxygen Saturation		

A comprehensive list of parameters available while monitoring with the HemoSphere Alta monitor and both a connected HemoSphere Alta Swan-Ganz patient cable and Oximetry cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
DO2	Oxygen Delivery	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
DO2I	Oxygen Delivery Indexed		
VO2	Oxygen Consumption		
VO2e	Estimated Oxygen Consumption when ScvO2 is being monitored		
VO2I	Oxygen Consumption Index		
VO2Ie	Estimated Oxygen Consumption Index when ScvO2 is being monitored		
GHI	global hypoperfusion index	Adult only	

A comprehensive list of parameters available while monitoring with the HemoSphere Alta monitor and both a connected HemoSphere Alta Swan-Ganz patient cable and pressure cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
CO_{20s}	20-second cardiac output	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 Alta monitor and a connected HemoSphere pressure cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
CO/ CI	Continuous Cardiac Output[1]/ Continuous Cardiac Index[1]	Adult only	Operating Room, Intensive Care Unit, Emergency Room
CVP	Central Venous Pressure		
DIA_{ART}	Systemic arterial diastolic blood pressure		
DIA_{PAP}	pulmonary artery diastolic blood		

	pressure		
	Systolic slope[2]		
Ea_{dyn}	Dynamic Arterial Elastance[2]		
MAP	Mean Arterial Pressure		
MPAP	Mean Pulmonary Arterial Pressure		
PPV	pulse pressure variation[1]		
PR	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}	Systolic Blood Pressure		
SYS_{PAP}	Systolic pulmonary artery blood pressure		
RVEDP	Right Ventricular End Diastolic Pressure		
RV dP/dt	Maximal right ventricular systolic slope		
SYS_{RVP}	Systolic Right Ventricular Pressure		
DIA_{RVP}	Right Ventricular Diastolic Pressure		
MRVP	Mean Right Ventricular Pressure		
PR_{RVP}	Right Ventricular Pulse Rate		
HPI	Acumen Hypotension Prediction Index		Operating Room, Intensive Care Unit
[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 Alta monitor and a connected HemoSphere pressure cable are listed below:

AFM output	Patient Population	Hospital Environment
Fluid Bolus Suggested	≥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 and pediatric patient populations while monitoring with the HemoSphere Alta monitor and both a connected HemoSphere pressure cable and oximetry cable are listed below:

Parameter	**Description**	**Patient Population**	**Hospital Environment**
DO_2	Oxygen Delivery	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		

Tissue oxygen saturation, StO_2, can be monitored with the HemoSphere Alta monitor and a connected ForeSight oximeter cable as listed below.

Parameter	Description	Patient Population	Hospital Environment
StO_2	Tissue oxygen saturation	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 Alta Advanced Monitor and a connected Pressure controller are listed below:

Parameter	Description	Patient Population	Hospital Environment
CO/CI	Continuous Cardiac Output/ Continuous Cardiac Index	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

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

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

VI. Comparison of Technological Characteristics with the Predicate Devices:

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

- Indication and Intended Use:
  The subject device has the same intended use and indication as the predicate.

- Technological characteristics:
  The subject device has the same technological characteristics as the predicate. Both subject and predicate devices use the same technologies and algorithms to provide hemodynamic monitoring.

- Accessories/Components: The subject and the predicate device both use the same accessories, Pressure controller, Heart Reference Sensor, ClearSight/Acumen IQ Cuffs for measurement of non-invasive parameters.

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

- Hardware: The subject device includes new hardware for the monitor with high resolution larger display to facilitates improved user interface. In addition, the new hardware integrates the existing subsystem modules available with the predicates device within the monitor (non-modular) to provide more accessible and faster set up.

- Software: The subject device includes an updated software architecture to support the new integrated hardware (non-modular).

- Graphical User Interface (GUI): The subject device includes an updated user interface to allow improved accessibility and utilization of multiple functions intuitively on one screen and provides additional customization options.

In addition, voice and gesture functionalities have been included for limited feature sets to provide user convenience.

A brief description of the key highlights of the subject HemoSphere Alta™ Advanced Monitoring Platform and a comparative overview with the predicate HemoSphere Advanced Monitoring Platform is provided below:

- **New Hardware –** *to integrate the existing HemoSphere subsystem modules:*

  The HemoSphere Alta Advanced Monitoring Platform includes new hardware for the monitor with higher resolution and larger display size that connects with the existing HemoSphere cables and accessories: HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere ForeSight Oximeter Cable, Pressure Controller, and Heart Reference Sensor.

  Contrary to the current HemoSphere Advanced Monitoring Platform, which incorporates a modular approach, the subject HemoSphere Alta™ Monitoring Platform integrates the existing HemoSphere subsystem modules (HemoSphere Swan Ganz Module, HemoSphere Technology Module, HemoSphere ClearSight Module) into the Monitor to bring together Edwards existing Critical Care technologies to a unified platform. This integrated system approach facilitates more accessible and faster set up.

- **Improved Graphical User Interface (GUI)-** *New GUI for the existing features and functionality currently available on the existing HemoSphere Platform:*

  The HemoSphere Alta™ Advanced Monitoring Platform includes a larger monitor display with an updated user interface. The updated user interface allows users to access, organize and utilize multiple functions intuitively on one screen, and it also provides additional customization options for users to select the information they need.

  In addition, optional voice and gesture functionalities have been included for limited feature sets of non-critical activities to provide user convenience.

- **Technologies and Algorithms-** *Uses the <u>same</u> core technologies and algorithms as the HemoSphere Platform:*

  - **Technologies:**

    The HemoSphere Alta Monitoring Platform uses the existing core technologies commercially available with the predicate HemoSphere Advanced Monitoring Platform. The following five (5) existing core technologies are integrated into the Subject HemoSphere Alta monitoring Platform:

    - Swan Ganz (Invasive)
    - Pressure using an Arterial line (Minimally Invasive)
    - Venous Oximetry (Invasive)
    - Tissue Oximetry (Non-Invasive)
    - ClearSight (Non-Invasive)

  - **Algorithms:**

    The HemoSphere Alta Monitoring Platform uses the existing algorithms commercially available with the predicate HemoSphere Advanced Monitoring Platform to facilitate hemodynamic monitoring.

- **Updated software architecture -** *to integrate the existing HemoSphere Advanced Monitoring Platform technologies:*

  The HemoSphere Alta Monitoring Platform includes an updated software architecture to support the new integrated hardware (non-modular). The software architecture for the subject HemoSphere Alta platform allows improved connection between the host software and hardware compared to the predicate HemoSphere platform to facilitate efficient integration between hardware and software and enhance maintenance and extendibility.

- **Modifications to the Labeling of the existing associated accessories to include HemoSphere Alta Monitoring Platform:**

  - The ClearSight/Acumen IQ™ Finger Cuffs (*Cleared in K160552 June 1, 2016, and K190130 June 21, 2019*) indications for use are being updated to add the HemoSphere Alta Monitoring Platform to the indications for use as part of this subject 510(k). No other changes are occurring to the ClearSight/Acumen IQ Finger Cuffs.

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

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

The following verification activities were performed in support of a substantial equivalence determination.

Performance Data:

Usability Study

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

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

System Verification (Non-Clinical Performance):

Completion of all verification and validation activities demonstrated that the subject devices meet their predetermined design and performance specifications. Verification activities performed confirmed that the differences in the design and materials used did not adversely affect the safety and effectiveness of the subject device.

Measured and derived parameters were tested using a bench simulation. Additionally, system integration and mechanical testing was successfully conducted to verify the safety and effectiveness of the device. All tests passed.

Edwards

Electrical Safety and Electromagnetic Compatibility (EMC)

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

Software Verification

Software verification testing were conducted, and documentation was provided per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". All tests passed.

Clinical Performance

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

Conclusion

The technological characteristics of the subject and predicate devices are identical. The HemoSphere Alta Advanced Monitoring Platform has successfully passed functional and performance testing, including software verification and validation, system integration, mechanical, electrical, human factor usability, and safety testing. The testing performed demonstrates that the HemoSphere Alta Advanced Monitoring Platform is substantially equivalent to the legally marketed predicates.