December 18, 2025

Edwards Lifesciences
Niharika Mirji
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K252533
Trade/Device Name: HemoSphere Alta Advanced Monitoring Platform (ALTAALL1; ALTACR1; ALTASR1)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ, MUD, DXN, DSB, FLL, QMS, QNL, QEM
Dated: November 17, 2025
Received: November 17, 2025

Dear Niharika Mirji:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252533	?

Please provide the device trade name(s). ?

HemoSphere Alta Advanced Monitoring Platform (ALTAALL1; ALTACR1; ALTASR1)

Please provide your Indications for Use below. ?

HemoSphere Alta™ Advanced Monitoring Platform with Swan-Ganz™ Technology

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere Alta Swan-Ganz™ Patient Cable and 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 Swan-Ganz™ Catheter and Swan-Ganz Jr™ 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 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.

When used in combination with a Swan-Ganz™ Catheter connected to a pressure cable and pressure transducer, the Smart Wedge™ Algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge™ Algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge™ 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 Smart Wedge™ Algorithm parameters.

HemoSphere Alta™ Advanced Monitoring Platform with HemoSphere™ Oximetry Cable

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere™ Oximetry Cable and 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 oximetry catheter indications for use statement for information on target patient population specific to the catheter being used.

HemoSphere Alta™ Advanced Monitoring Platform with HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor - Pressure Cable

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable is indicated for use in adult and pediatric 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 FloTrac™ Sensor, FloTrac Jr™ Sensor, Acumen IQ™ Sensor, and TruWave™ Disposable Pressure Transducer indications for use statements for information on target patient populations specific to the sensor/transducer being used.

The Acumen Hypotension Prediction Index™ Software Feature (HPI™ Parameter)
provides the clinician with physiological insight into a patient's likelihood of future hypotensive events 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™ Parameter.

When used in combination with the HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable connected to a compatible Swan-Ganz™ Catheter, the 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.

When used in combination with the HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable connected to a compatible Swan-Ganz™ Catheter, the Right Ventricular Cardiac Output (RVCO) feature provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVCO algorithm is intended for use in surgical or non-surgical patients over 18 years of age that require advanced hemodynamic monitoring. The Right Ventricular Cardiac Output provides a continuous cardiac output and derived parameters.

The Cerebral Autoregulation Index (CAI) algorithm is an informational index intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between Mean Arterial Pressure (MAP) and the Absolute Levels of Blood Oxygenation Saturation (StO2) in patient's cerebral tissue. MAP is acquired by the HemoSphere™ Pressure Cable and StO2 is acquired by the ForeSight™ Oximeter Cable. CAI is intended for use in patients over 18 years of age receiving advanced hemodynamic monitoring. CAI is not indicated to be used for treatment of any disease or condition and no therapeutic decisions should be made based solely on the Cerebral Autoregulation Index (CAI) algorithm.

HemoSphere Alta Advanced Monitoring Platform 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™ Advanced Monitoring Platform.

• 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.

The algorithm for measurement of blood hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight™ Oximeter Cable and noninvasive ForeSight IQ™ Sensors in cerebral locations.

HemoSphere Alta™ Advanced Monitoring Platform with Non-invasive technology

The HemoSphere Alta™ Monitor when used with the pressure controller and a compatible finger cuff are indicated for adult and pediatric patients 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 non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere Alta™ Advanced Monitor and compatible finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. Refer to the non-invasive finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

The Acumen Hypotension Prediction Index™ Software Feature (HPI™ Parameter) provides the clinician with physiological insight into a patient's likelihood of future hypotensive events 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™ Parameter.

HemoSphere Alta Advanced Monitoring Platform 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 HemoSphere Alta AFM cable and Acumen IQ fluid meter.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary – HemoSphere Alta Advanced Monitoring Platform

I. Submitter:

Sponsor	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number	2015691
Primary Contact Person	Niharika Niranjan Mirji Senior Specialist, Regulatory Affairs Advanced Patient Monitoring, Becton, Dickinson and Company 17200 Laguna Canyon Rd Irvine, CA 92618 Email: niharika.niranjan.mirji@bd.com
Secondary Contact Person	Chirag Shah Director, Regulatory Affairs Advanced Patient Monitoring, Becton, Dickinson and Company 17200 Laguna Canyon Rd Irvine, CA 92618 Email: chirag.shah@bd.com
Date Prepared	December 08, 2025

II. Device Information:

Platform Name (Name of Device)	HemoSphere Alta Advanced Monitoring Platform (ALTAALL1; ALTACR1; ALTASR1)
Trade Name:	HemoSphere Alta All-on-One monitor HemoSphere Alta Advanced Cardiac Monitor HemoSphere Alta Advanced Smart Recovery Monitor
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 Predicative Cardiovascular Indicator	21 CFR 870.2210
	System, Catheter or Guidewire, Steerable (Magnetic) Steerable catheter control system	21 CFR 870.1290

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
	QEM	Class II

III. Predicate Device:

Primary Predicate Device: The HemoSphere Alta Advanced Monitoring Platform (K242451 cleared on December 09, 2024) is the base device on which the software modifications have been implemented. It has been utilized for substantial equivalence in terms of the graphical user interface (GUI) used, indication for use, intended use, technological characteristics, accessories, basic device functionality, CAI, and cybersecurity updates

IV. Device Description:

Device Description: The HemoSphere Alta Advanced Monitoring Platform is the next-generation platform that provides a means to interact with and visualize hemodynamic and volumetric data on a screen. It incorporates a comprehensive view of patient hemodynamic parameters with an intuitive and easy user interface. The HemoSphere Alta Advanced Monitoring Platform is designed to provide monitoring of cardiac flow with various core technologies coupled with other technologies-based features such as Algorithms and Interactions. It integrates existing hemodynamic monitoring technologies into a unified platform.

V. Indications for Use:

Indications for Use:

HemoSphere *Alta*™ Advanced Monitoring Platform with Swan-Ganz™ Technology

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere Alta Swan-Ganz™ Patient Cable and 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 Swan-Ganz™ Catheter and Swan-Ganz Jr™ 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 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.

When used in combination with a Swan-Ganz™ Catheter connected to a pressure cable and pressure transducer, the Smart Wedge™ Algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge™ Algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge™ 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 Smart Wedge™ Algorithm parameters.

HemoSphere Alta™ Advanced Monitoring Platform with HemoSphere™ Oximetry Cable

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere™ Oximetry Cable and 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 oximetry catheter indications for use statement for information on target patient population specific to the catheter being used.

HemoSphere Alta™ Advanced Monitoring Platform with HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor - Pressure Cable

The HemoSphere Alta™ Advanced Monitor when used with the HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable is indicated for use in adult and pediatric 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 FloTrac™ Sensor, FloTrac Jr™ Sensor, Acumen IQ™ Sensor, and TruWave™ Disposable Pressure Transducer indications for use statements for information on target patient populations specific to the sensor/transducer being used.

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When used in combination with the HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable connected to a compatible Swan-Ganz™ Catheter, the Right Ventricular Cardiac Output (RVCO) feature provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVCO algorithm is intended for use in surgical or non-surgical patients over 18 years of age that require advanced hemodynamic monitoring. The Right Ventricular Cardiac Output provides a continuous cardiac output and derived parameters.

The Cerebral Autoregulation Index (CAI) algorithm is an informational index intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between Mean Arterial Pressure (MAP) and the Absolute Levels of Blood Oxygenation Saturation (StO_2) in patient's cerebral tissue. MAP is acquired by the HemoSphere™ Pressure Cable and StO_2 is acquired by the ForeSight™ Oximeter Cable. CAI is intended for use in patients over 18 years of age receiving advanced hemodynamic monitoring. CAI is not indicated to be used for treatment of any disease or condition and no therapeutic decisions should be made based solely on the Cerebral Autoregulation Index (CAI) algorithm.

HemoSphere Alta Advanced Monitoring Platform 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™ Advanced Monitoring Platform.

- 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.

The algorithm for measurement of blood hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight™ Oximeter Cable and noninvasive ForeSight IQ™ Sensors in cerebral locations.

HemoSphere Alta™ Advanced Monitoring Platform with Non-invasive technology

The HemoSphere Alta™ Monitor when used with the pressure controller and a compatible finger cuff are indicated for adult and pediatric patients 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 non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere Alta™ Advanced Monitor and compatible finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. Refer to the non-invasive finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

The Acumen Hypotension Prediction Index™ Software Feature (HPI™ Parameter) provides the clinician with physiological insight into a patient's likelihood of future hypotensive events 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™ Parameter.

HemoSphere Alta Advanced Monitoring Platform 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 HemoSphere Alta AFM cable and Acumen IQ fluid meter.

VI. Intended Use:

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 oximetry catheters, Swan-Ganz™/Swan-Ganz Jr™/Swan-Ganz IQ™ Catheters, FloTrac™ Sensors, FloTrac Jr™ Sensors, Acumen IQ™ Sensors, TruWave™ Disposable Pressure Transducers, ForeSight™ /ForeSight

Jr™/ForeSight IQ™ Sensors, Acumen IQ™ Fluid Meter, and ClearSight™/ClearSight Jr™/Acumen IQ™/Acumen IQ Plus™ Finger Cuffs.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected HemoSphere Alta Swan-Ganz™ Patient Cable are listed in the table 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		
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 Alta™ Advanced Monitoring Platform and a connected HemoSphere™ Oximetry Cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
SvO_2	Mixed Venous Oxygen Saturation	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
$ScvO_2$	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
DO_2	Oxygen delivery	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
DO_2I	Oxygen delivery index		
VO_2	Oxygen consumption		
VO_2e	estimated oxygen consumption when ScvO2 is being monitored		
VO_2I	Oxygen consumption index		
VO_2Ie	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™ Advanced Monitoring Platform 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 input		
SV_{20s}	20-second stroke volume		
SVI_{20s}	20-second stroke volume index		
PAOP	Pulmonary artery occlusion pressure[2]		
RVEDP	Right Ventricular End Diastolic Pressure		
RV dP/dt	Maximal Right Ventricular Systolic slope[2]		
SYS_{RVP}	Systolic Right Ventricular Pressure		

DIA_{RVP}	Diastolic Right Ventricular Pressure		
MRVP	Mean Right Ventricular Pressure[2]		
CO_{RV}	Right Ventricular cardiac output		
CI_{RV}	Right Ventricular cardiac input		
CPO_{RV}	Right Ventricular cardiac power output		
CPI_{RV}	Right Ventricular cardiac power index		
SV_{RV}	Right Ventricular Stroke Volume[2]		
SVI_{RV}	Right Ventricular Stroke Volume Index[2]		
PR_{RVP}	Right Ventricular Pulse Rate[2]		
SVR_{RV}	Right Ventricular Systemic vascular Resistance[2,3]		
$SVRI_{RV}$	Right Ventricular Systemic vascular Resistance Index[2,3]		

[1]20-second flow parameters are only available if the 20s flow parameter feature is enabled. Please Contact your local sales representative for more information on enabling this advanced feature.
[2]RVP and RVCO parameters are available when using a Swan-Ganz IQ™ Catheter.
[3]SVR_{RV} and $SVRI_{RV}$ values are calculated using CO_{RV}/CI_{RV} values originating from the right ventricle via a Swan-Ganz IQ™ Catheter, respectively.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
CO	Continuous Cardiac Output[1]	Adult and Pediatric ≥ 12 years of age	Operating Room, Intensive Care Unit, Emergency Room
CI	Continuous Cardiac Index[1]		
CPO	Cardiac Power Output		
CPI	Cardiac Power Index		
DIA_{ART}	Systemic arterial diastolic blood pressure		
MAP	Mean Arterial Pressure		
PPV	Pulse pressure variation[1]		
PR	Pulse rate		
SV	Stroke Volume[1]		
SVI	Stroke Volume Index[1]		
SVR	Systemic Vascular Resistance[1]		
SVRI	Systemic Vascular Resistance[1] Index		
SVV	Stroke Volume Variation[1]		

SYS_{ART}	Systemic Arterial Systolic Blood Pressure		
CVP	Central Venous Pressure	Adult only	Operating Room, Intensive Care Unit
DIA_{RVP}	right ventricular diastolic pressure		
MPAP	Mean Pulmonary Arterial Pressure		
SYS_{RVP}	Right Ventricular Systolic Pressure		
RVEDP	Right ventricular End Diastolic Pressure		
MRVP	Mean Right Ventricular Pressure		
PR_{RVP}	Right Ventricular Pulse Rate		
RV dP/dt	Right Ventricular Systolic Slope		
SYS_{PAP}	Systolic Pulmonary artery blood pressure		
DIA_{PAP}	Pulmonary artery diastolic blood pressure		
dp/dt	Systolic slope[2]		
Ea_{dyn}	Dynamic Arterial Elastance[2]		
HPI	Acumen Hypotension Prediction Index		
[1]FloTrac™ Parameters are available when using an advanced arterial sensor (FloTrac™ Sensor, FloTrac Jr™ Sensor or Acumen IQ™ Sensor) [2]HPI™ Parameters are available when using an Acumen IQ™ sensor			

A list of Acumen Assisted Fluid Management (AFM™ Algorithm) outputs available for surgical patients ≥18 years of age while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor – Pressure Cable are listed below:

AFM Algorithm output	**Patient Population**	**Hospital Environment**
Fluid Bolus Suggested	≥18 years of age only	Operating Room
Test Bolus Suggested		
Fluid not Suggested		
Suggestion suspended		
Bolus in progress		
Bolus complete		
Bolus Complete; Analyzing Hemodynamic Response		
Tracked Case Vol.		
Flow Rate		
Bolus Volume		

Note: AFM™ Algorithm outputs are available when using an Acumen IQ™ Sensor and if the AFM feature is activated. Flow rate mL/hr and Bolus Volume are visible when using automatic fluid tracking mode.

Additional parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform 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 index		
VO_2	Oxygen consumption		
VO_2I	Oxygen consumption index		
VO_2e	estimated oxygen consumption when ScvO2 is being monitored		
VO_2Ie	estimated oxygen consumption index when ScvO2 is being monitored		

Tissue oxygen saturation, StO_2, can be monitored with the HemoSphere™ Alta Advanced Monitoring Platform 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		
tHb	Total Hemoglobin	Adults and transitional adolescents ≥40 kg	
Total hemoglobing (tHb) is available when monitoring using HemoSphere ForeSight™ Oximeter Cable and Foresight IQ™ Sensors in cerebral locations			

Additional parameters available for adult populations while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and both a connected HemoSphere™ Pressure Cable or HemoSphere™ Alta Monitor- Pressure Cable and ForeSight™ Oximeter Cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
CAI	Cerebral Adaptive Index[1]	Adult only	Operating Room, Intensive Care Unit, Emergency Room
DO_2	Oxygen Delivery[2]		
DO_2I	Oxygen Delivery Index[2]		

[1]CAI parameter is available when using a ForeSight IQ sensor and if the CAI feature is enabled.
[2]DO_2/DO_2I parameter is available when tHb is being monitored and when SpO_2 is available through manual entry.

Additional parameters available for adult patient populations while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected HemoSphere™ Pressure Cable or HemoSphere Alta™ Monitor– Pressure Cable, ForeSight™ Oximeter Cable and oximetry cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
VO_2	Oxygen consumption	Adult only	Operating Room, Intensive Care Unit and Emergency Room
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		
VO_2 parameters are available when tHb is being monitored and when SpO_2 is available through manual entry			

A comprehensive list of parameters available while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected pressure controller are listed below:

Parameter	Description	Patient Population	Hospital Environment
CO	Continuous Cardiac Output	Adult and pediatric ≥ 12	Operating Room, Intensive Care Unit, Emergency Room
CI	Continuous Cardiac Index		
CPO	Cardiac Power Output		
CPI	Cardiac Power Index		
DIA	Arterial diastolic blood pressure		
SYS	Systolic Blood Pressure		
MAP	Noninvasive Mean Arterial Pressure		
PPV	pulse pressure variation		
PR	Noninvasive Pulse rate		
SV	Stroke Volume		
SVI	Stroke Volume Index		
SVR	Systemic Vascular Resistance		

SVRI	Systemic Vascular Resistance Index		
SVV	Stroke Volume Variation		
dP/dt	Maximal slope of the arterial pressure upstroke[1]	Adult only	
Ea_{dyn}	Dynamic Arterial Elastance[1]		
HPI	Acumen Hypotension Prediction Index[1]		
[1]HPI™ Parameters are available when using an Acumen IQ™ Finger Cuff and heart reference sensor (HRS) 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.			

Additional parameters available for adult patient populations while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and both a connected pressure controller and ForeSight™ Oximeter 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 index		
Continuous DO_2/DO_2I parameter is available when tHb is being monitored and when SpO_2 is available through manual entry.			

Additional parameters available for adult patient populations while monitoring with the HemoSphere Alta™ Advanced Monitoring Platform and a connected pressure controller, ForeSight™ Oximeter Cable, and oximetry cable are listed below:

Parameter	Description	Patient Population	Hospital Environment
VO_2	Oxygen consumption	Adult only	Operating Room, Intensive Care Unit and Emergency Room
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		
Continuous VO_2 parameters are available when tHb is being monitored and when SpO_2 is available through manual entry.			

VII. Comparison of Technological Characteristics with the Predicate Devices:

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

- Hardware: The subject device uses the same platform as the predicate (K242451, cleared on December 09, 2024).
- Technological Characteristics: The new features included in the subject device have similar technological characteristics as the predicate device.

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

- Indications and Intended Use: The subject and predicate devices have no modification other than branding and changes for better clarifications in the Indications and Intended Use statements.
- Software: The subject device includes updated software to support the Smart Pressure Controller and other features.
- Graphical User Interface (GUI): The subject device includes an updated graphical user interface to accommodate the new features such as the Smart Pressure Controller, Oxygen Delivery (DO_2) and Oxygen Consumption (VO_2) trending screens, and Cerebral Autoregulation Index secondary screens.
- Accessories/Components: Addition of the cleared Smart Pressure Controller (PC1Q) and cleared Acumen IQ Plus finger cuff (AIQCA2) for use with the subject device.

The complete list of modifications included in the HemoSphere Alta Advanced Monitoring Platform as part of this subject 510(k) is provided below:

- Addition of two (2) previously cleared devices (Smart Pressure Controller and Acumen IQ Plus finger cuffs) for use with the HemoSphere Alta Advanced Monitoring Platform
- Four (4) software modifications to the HemoSphere Alta™ Advanced Monitoring Platform
    i. The existing ClearSight subsystem and Alta monitor GUI for use with the Smart Pressure Controller (Model PC1Q) and Acumen IQ Plus finger Cuff (Model AIQCA2)
    ii. Enable display of Oxygen Delivery (DO2) and Oxygen Consumption (VO2) parameters (as a trendline).
    iii. Add CAI secondary screen
    iv. Cybersecurity updates
- Updates to the HemoSphere Alta™ Operators' Manual associated with the device modifications

VIII. Performance Data:

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

Usability Study

A Usability study was conducted per FDA's guidance document "*Applying Human Factors and Usability Engineering to Medical Devices*" issued February 3, 2016 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. The HemoSphere Alta monitoring platform has been found to be safe and effective for the intended users, uses, and use environments. All acceptance criteria were met for human factors validation. The test demonstrates usability of the HemoSphere Alta monitoring platform's critical tasks associated with the modified features of the HemoSphere Alta monitoring platforms and provides objective evidence that the features meet their user needs and intended use.

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 was successfully conducted to verify the safety and effectiveness of the device. All tests passed.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject HemoSphere Alta Advanced Monitoring Platform, consisting of the HemoSphere Alta 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, IEC 60529-1, and IEC 80601-2-49. All tests passed.

Software Verification

Software verification testing was 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". The HemoSphere Alta Advanced Monitor was

put through extensive software verification testing to ensure that it is safe for use and all tests passed thus demonstrating the substantial equivalence to the predicate devices.

Clinical Performance

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

IX. Conclusion:

The HemoSphere Alta Advanced Monitoring Platform has undergone comprehensive functional and performance testing, including software verification and validation, system integration, electrical, human factors usability, and safety testing. All tests passed and confirmed the device performs as intended and meets applicable performance criteria.

The information provided in this premarket notification including the detailed device description, intended use, indications for use, technological characteristics, and performance data supports that the subject device does not raise new questions of safety or effectiveness. The device maintains the same core technology and intended use as the predicate devices.

Based on the totality of evidence submitted, the HemoSphere Alta Advanced Monitoring Platform has been demonstrated to be substantially equivalent to the legally marketed predicate devices, in accordance with the requirements of FDA guidance *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, July 2014.*