December 9, 2024

Edwards LifeSciences
Varad Raghuwanshi
Director, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K242451
Trade/Device Name: HemoSphere Alta Advanced Monitoring Platform (ALTAALL1/ALTCR1/ALTASR1);
HemoSphere Alta- monitor pressure cable (HEMAPSC200);
Acumen AFM cable- HemoSphere Alta monitor (HEMAFM100)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQE, QAQ, MUD, DXN, DSB. FLL, QMS, QNL, QEM
Dated: August 16, 2024
Received: August 16, 2024

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K242451

Device Name
HemoSphere Alta Advanced Monitoring Platform (ALTAALL1/ALTCR1/ALTASR1);
HemoSphere Alta- monitor pressure cable (HEMAPSC200);
Acumen AFM cable- HemoSphere Alta monitor (HEMAFM100)

Indications for Use *(Describe)*
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 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 Edwards Lifesciences 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 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.

HemoSphere Alta Advanced Monitor with HemoSphere Pressure Cable or HemoSphere Alta Monitor Pressure Cable

The HemoSphere Alta 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 hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac, FloTrac Jr, 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 software feature 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 Hypotension Prediction Index (HPI) parameter.

When used in combination with the Swan-Ganz technology 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.

When used in combination with the HemoSphere 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 Adaptive Index (CAI) Algorithm is an informational index to help assess 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 or HemoSphere Alta 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 Adaptive Index (CAI) Algorithm.

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.

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.

Acumen IQ Fluid Meter
The Acumen IQ fluid meter is a sterile single use device that is intended to be used with the HemoSphere Alta 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.

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.

The Edwards Algorithm for Measurement of Blood Hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults and transitional adolescents ≥ 40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight Oximeter Cable and ForeSight IQ Sensors in cerebral locations.

HemoSphere Alta Advanced Monitor with ClearSight Technology

The HemoSphere Alta Monitor when used with the HemoSphere ClearSight technology, pressure controller and a compatible Edwards finger cuff are indicated for Adult and Pediatric patients 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 Alta 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 and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical patients 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.

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
Director, Regulatory Affairs
One Edwards Way
Irvine, CA 92614
Telephone: (949) 756-4502
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**Date Prepared:** December 5, 2024

## II. Device Information:

**Platform Name (Name of the Device):** HemoSphere Alta Advanced Monitoring Platform (ALTAALL1/ ALTCR1/ALTASR1)

**Trade Name:**

HemoSphere Alta Advanced Cardiac Monitor
HemoSphere Alta Advanced Smart Recovery Monitor
HemoSphere Alta All-on-One monitor
HemoSphere Alta- Monitor Pressure Cable (HEMAPSC200)
HemoSphere Alta AFM Cable (HEMAFM100)
Right Ventricular Cardiac Output Feature

**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 |
| | 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:**

- HemoSphere Alta Advanced Monitoring Platform manufactured by Edwards Lifesciences, K232294, cleared on October 31st, 2023. It 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, cardiac output algorithms, accessories, basic device functionality, new configuration Pressure cable (HEMAPSC200), optional feature to use pulse rate for associated derived parameter calculation, updated GHI algorithm and the subject Right Ventricular Cardiac Output (RVCO) Algorithm.

**Additional Predicate Devices:**

- HemoSphere Advanced Monitoring Platform by Edwards Lifesciences, K223865, cleared on June 9th, 2023, utilized for AFM automated fluid tracking and the automatic zeroing of the Heart reference sensor feature.
- Cerebral Adaptive Index (CAI) algorithm by Edwards Lifesciences, K223651, cleared on May 26, 2023, utilized for the Cerebral Adaptive Index (CAI) parameter.
- Edwards Algorithm for Measurement of Blood Hemoglobin by Edwards Lifesciences, K230612, cleared on November 17th, 2023, utilized for the Total Blood Hemoglobin (tHb) parameter.

- Smart Wedge algorithm by Edwards Lifesciences, K230579 cleared on August 17th, 2023, utilized for the Smart Wedge functionality.
- Acumen Hypotension Prediction Index (HPI) algorithm by Edwards Lifesciences, K230057, cleared on June 8th, 2023, utilized for the HPI Adjustable MAP (Hypotension threshold) feature.
- Swan-Ganz Catheters, FloTrac sensors, ClearSight finger cuffs, HemoSphere Advanced Monitoring Platform by Edwards Lifesciences, K231248, cleared on September 21, 2023, for Pediatric patients ≥ 12 years of age Indication expansion when used with Swan-Ganz catheters, FloTrac sensors, ClearSight finger cuffs.

## 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. 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 Edwards existing Critical Care technologies into a unified platform.

The Right Ventricular Cardiac Output (RVCO) feature is a machine-learning algorithm that calculates and displays continuous cardiac output ($CO_{RV}$) from the right ventricle using as inputs the right ventricular pressure waveform and derived right ventricular pressure parameters such as $SYS_{RVP}$, $DIA_{RVP}$, MRVP, RVEDP, $PR_{RV}$ and Max RV dP/dt from the existing Right Ventricular Pressure (RVP) algorithm and if available, intermittent cardiac output (iCO).

## 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 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 Edwards Lifesciences 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 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 or HemoSphere Alta Monitor Pressure Cable**

The HemoSphere Alta 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 hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

The Edwards Lifesciences Acumen Hypotension Prediction Index software feature 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 Hypotension Prediction Index (HPI) parameter.

When used in combination with the Swan-Ganz technology 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.

When used in combination with the HemoSphere 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 Adaptive Index (CAI) Algorithm is an informational index to help assess 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 or HemoSphere Alta 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 Adaptive Index (CAI) Algorithm.

**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.
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.

Acumen IQ Fluid Meter
The Acumen IQ fluid meter is a sterile single use device that is intended to be used with the HemoSphere Alta 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.

**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.

The Edwards Algorithm for Measurement of Blood Hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults and transitional adolescents ≥ 40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight Oximeter Cable and ForeSight IQ Sensors in cerebral locations.

**HemoSphere Alta Advanced Monitor with ClearSight Technology**

The HemoSphere Alta Monitor when used with the HemoSphere ClearSight technology, pressure controller and a compatible Edwards finger cuff are indicated for Adult and Pediatric patients 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 Alta 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 and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical patients 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.

**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/Swan-Ganz Jr/Swan-Ganz IQ catheters and oximetry catheters, FloTrac/FloTrac Jr sensors, Acumen IQ sensors, TruWave DPTs, ForeSight /ForeSight Jr sensors/ForeSight IQ sensor, Acumen IQ fluid meter and ClearSight/ClearSight Jr/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 | | |
| CPO | Cardiac Power 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 | | |
| 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 | | |
| $DIA_{RVP}$ | Right Ventricular Diastolic Pressure[2] | | |
| MRVP | Mean Right Ventricular Pressure[2] | | |
| $CO_{RV}$ | Right ventricular cardiac output[2] | | |
| $CI_{RV}$ | Right ventricular cardiac index[2] | | |
| $CPO_{RV}$ | Right ventricular cardiac power output[2] | | |
| $CPI_{RV}$ | Right ventricular cardiac power index[2] | | |
| $SV_{RV}$ | Right Ventricular Stroke Volume[2] | | |
| $SVI_{RV}$ | Right Ventricular Stroke Volume Index[2] | | |
| $PR_{RVP}$ | Right Ventricular Pulse Rate[2] | | |
| $CO_{RV}$ | Right Ventricular Cardiac Output[2] | | |

[1] 20-second flow parameters are only available if the 20s flow parameter feature is enabled. Please Contact your local Edwards representative for more information on enabling this advanced feature.
[2] RVP and RVCO parameters are available when using a Swan-Ganz IQ catheter.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta monitor and a connected HemoSphere pressure cable or HemoSphere Alta pressure Cable are listed below:

| **Parameter** | **Description** | **Patient Population** | **Hospital Environment** |
|---|---|---|---|
| CO/ CI | Continuous Cardiac Output[1]/ Continuous Cardiac Index[1] | Adult and Pediatric ≥ 12 years of age | Operating Room, Intensive Care Unit, Emergency Room |
| CVP | Central Venous Pressure | | |
| CPO | Cardiac Power output | | |
| CPI | Cardiac Power index | | |
| $DIA_{ART}$ | 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 | Adult Only | Operating Room, Intensive Care Unit |
| 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 | | |
| *[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. | | |
| 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 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 | | |

Edwards

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 | | |
| tHb | Total Hemoglobin | Adults and transitional adolescents ≥40 kg | |
| Total hemoglobin (tHb) is available when monitoring using a HemoSphere ForeSight Oximeter Cable and two Foresight IQ Sensors in cerebral locations | | | |

comprehensive list of parameters available for adult populations while monitoring with the HemoSphere Alta monitor and both a connected HemoSphere pressure cable or HemoSphere Alta Pressure Cable and a connected 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 |
| [1] CAI parameter is available when using a ForeSight IQ sensor and if the CAI feature is enabled. | | | |

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 | Continuous Cardiac Output | Adult and pediatric ≥ 12 | Operating Room, Intensive Care Unit, Emergency Room |
| CPO | Cardiac Power Output | | |
| CI | Continuous Cardiac Index | | |
| DIA | arterial diastolic bloodpressure | | |
| SYS | Systolic Blood Pressure | | |
| MAP | Mean Arterial Pressure | | |
| PPV | pulse pressure variation | | |
| PR | Pulse rate | | |
| SV | Stroke Volume | | |
| SVI | Stroke Volume Index | | |
| SVR | Systemic Vascular Resistance | | |
| SVRI | Systemic Vascular Resistance Index | | |
| SVV | Stroke Volume Variation | | |
| dP/dt | systolic slope | Adult only | |
| Eadyn | Dynamic Arterial Elastance1 | | |
| HPI | Acumen Hypotension Prediction Index[1] | | |
| [1]HPI parameters are available when using an Acumen IQ finger cuff and heart reference sensor (HRS)<br>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 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:

- Hardware: The subject device uses the same platform as the predicate (K232294, cleared October 31st, 2023). Additionally, the updated hardware configurations for the cables: HemoSphere Alta Pressure Cable and HemoSphere Alta AFM Cable remain identical in terms of the functionality, intended use and indication to their respective predicate devices.

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

- Technological characteristics:
  The new features/algorithm included in the subject device have the same technological characteristics as their respective predicate devices.

- Accessories/Components: The subject and the predicate device both use the same accessories and components, Pressure controller, Heart Reference Sensor, Acumen fluid meter.

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

- Hardware: The subject device includes new hardware configuration of the configurations for the cables: HemoSphere Alta Pressure Cable and HemoSphere Alta AFM Cable. The updated configuration includes the modified connectors and updated design for user convenience.

- Software: The subject device includes an updated software to support the new integrated algorithms and features.

- Graphical User Interface (GUI): The subject device includes an updated graphical user interface to accommodate new integrated algorithms and features.

- New Algorithm: The subject HemoSphere Alta Advanced Monitoring Platform includes a new Right Ventricular Cardiac Output (RVCO) algorithm, which uses the existing technologies, RVP and iCO algorithms of the HemoSphere Alta Advanced monitoring platform device (K232294, cleared October 31, 2023).

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 features and/or algorithms for the HemoSphere Alta Advanced Monitoring Platform (original K232294, cleared October 31st, 2023):**

- Cerebral Adaptive Index (CAI):

  The existing Cerebral Adaptive Index (CAI) Algorithm (K223651, cleared May 26th, 2023) has been integrated into the HemoSphere Alta Advanced Monitoring.

- Edwards Algorithm for Measurement of Blood Hemoglobin (tHb):

  The existing Edwards Algorithm for Measurement of Blood Hemoglobin (K230612, cleared Nov 17th, 2023) has been integrated into the HemoSphere Alta Advanced Monitoring.

- Smart Wedge Algorithm:

The Smart Wedge Algorithm (K230579, cleared August 18th, 2023) has been integrated into the HemoSphere Alta Advanced Monitoring.

- Right Ventricular Cardiac Output (RVCO) Algorithm:

  The RVCO algorithm is a new algorithm that uses the right ventricular pressure waveform to calculate continuous cardiac output. The right ventricular cardiac output ($CO_{RV}$) parameter provides an additional option for the measurement of cardiac output and trends it continuously for use in the surgical and nonsurgical setting. The algorithm is based on the physiological relationship between flow and pressure in the pulmonary cardiovascular system, and it was trained with large-scale data to capture this relationship between pulmonary flow and right ventricular pressure.

- HemoSphere Alta ™ monitor Pressure cable (HEMAPSC200):

  A New configuration of the existing HemoSphere Pressure Cable (HEMPSC100) is being introduced to provide improved user interface.

- **Modification to the existing elements of the HemoSphere Alta Advanced Monitoring Platform:**

- Acumen Assisted Fluid Management (AFM) – Automatic bolus tracking with Acumen AFM cable:

  The Acumen Assisted Fluid Management (AFM) feature has been updated to allow for an automated fluid tracking mode cleared in K223865 on June 9th, 2023, for HemoSphere Advanced Monitoring Platform.
  Similar to the predicate device, this automated fluid tracking mode for the AFM software feature is achieved via a modified Acumen AFM cable and the existing AFM fluid meter.
  Additionally, for user convenience, the automatic bolus tracking feature can now also be used independently in "Fluid Meter Only" mode to track fluid administration. In this mode, users can track fluid delivery via an existing Acumen fluid meter instead of manually tracking and logging. During this mode, the AFM algorithm will be disabled, and the user will not get any bolus suggestions.

- Modification to the existing Acumen Hypotension Prediction Index (HPI) feature:

  The existing HPI feature for HemoSphere Alta Advanced Monitoring Platform has been modified to include the existing Acumen HPI variable MAP target feature that was cleared in K230057.

- Modification to the existing Global Hypoperfusion Index (GHI) feature:

  The existing GHI feature is being updated to utilize RVCO input in addition to the CCO input that was previously cleared in K232294 on October 31st, 2023. Now, the user will have the option to utilize either RVCO or CCO.

- Modification to provide an option to use the existing pulse rate instead of heart rate input for calculating associated parameters:

  The HemoSphere Alta Advanced Monitoring Platform currently requires a heart rate (HR) signal to be computed to calculate parameters such as EDV, EDVI, RVEF, sEDV, sEDVI, SV and SVI parameters, Modifications have been made to allow users to utilize existing Pulse Rate for the parameter calculation in place of heart Rate (HR), now the users will have the option to utilize PR (from an ART signal).

- Miscellaneous Graphical User Interface (GUI) updates: The HemoSphere Alta Advanced Monitoring Platform GUI has been updated to support the above-mentioned and to provide user convenience.

- **Modifications to the labeling to address the device modifications and to include the HemoSphere Alta Monitoring Platform to the existing compatible devices labelling:**

- Indication update to include pediatric patients ≥ 12 years of age (*Cleared in K231248 on September 21, 2023, on HemoSphere Advanced Monitoring Platform*):

The indication for use for the HemoSphere Alta Advanced Monitoring Platform when used with Swan-Ganz catheters, FloTrac sensors, ClearSight finger cuffs has been updated to include pediatric patients ≥ 12 years of age.

- Indication update to include Acumen Hypotension Prediction Index (HPI) modification cleared in K230057 on June 8, 2023:

  The Acumen Hypotension Prediction Index (HPI) feature indication has been updated to include variable MAP threshold and patient population that include non-surgical patient during non-invasive monitoring cleared in K230057 on June 8, 2023.

- The Acumen IQ Fluid Meter (*Cleared in K223865 on June 9th, 2023)* intended use is being updated to add compatibility with the Acumen AFM cable -HemoSphere Alta as part of this subject 510(k).

- ForeSight IQ Large Sensor (FSESLIQ):

  A rebranded ForeSight IQ Large Sensor configuration of the existing ForeSight Large Sensor (FSESL) is being introduced.

**Performance Data:**

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

**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.

**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). However, clinical data (waveforms) were collected in support of the design and validation of the RVCO algorithm.

**Conclusion**

The technological characteristics of the subject and predicate devices are similar. 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.