July 23, 2025

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

Re: K243781
Trade/Device Name: HemoSphere Advanced Monitor (HEM1); HemoSphere Technology Module (HEMTOM10); HemoSphere ClearSight Module (HEMCSM10); Smart Pressure Controller (PC1Q); Acumen IQ Plus Finger Cuff (AIQCA2); HemoSphere Pressure Cable (HEMPSC100); HemoSphere Vita Monitor (HEMVITA1); HemoSphere Vita Technology Module (HEMVTOM1); HemoSphere VitaWave module (HEMVWM1); VitaWave Plus finger cuff (VWCA2)
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
Dated: December 7, 2024
Received: December 9, 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

Indications for Use

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

510(k) Number *(if known)*
K243781

Device Name
HemoSphere Advanced Monitor (HEM1); HemoSphere Technology Module (HEMTOM10); HemoSphere ClearSight Module (HEMCSM10);Smart Pressure Controller (PC1Q); HemoSphere Pressure Cable (HEMPSC100); Acumen IQ Plus Finger Cuff (AIQCA2); HemoSphere Vita Technology Module (HEMVTOM1);HemoSphere VitaWave module (HEMVWM1);VitaWave Plus fin

Indications for Use *(Describe)*
HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module

The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) and derived hemodynamic parameters in a hospital environment. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. It may also be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards Swan-Ganz catheter and Swan-Ganz Jr catheter indications for use statements for information on target patient population specific to the catheter being used. Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

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

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

HemoSphere Advanced Monitor with HemoSphere Pressure Cable

The HemoSphere advanced monitor when used with the HemoSphere pressure cable is indicated for use in 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 Edwards 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 Edwards 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 Acumen Hypotension Prediction Index (HPI) parameter.

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

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

The Acumen Assisted Fluid Management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

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

HemoSphere Advanced Monitor with HemoSphere Technology Module and ForeSight Oximeter Cable

The non-invasive ForeSight oximeter cable is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no flow ischemic states. The ForeSight Oximeter Cable is also intended to monitor relative changes of total hemoglobin of blood under the sensors. The ForeSight Oximeter Cable is intended to allow for the display of StO2 and relative change in total hemoglobin on the HemoSphere advanced monitor.

- When used with large sensors, the ForeSight Oximeter Cable is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with medium sensors, the ForeSight Oximeter Cable is indicated for use on pediatric subjects ≥3 kg.
- When used with small sensors, the ForeSight Oximeter Cable is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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

HemoSphere Advanced Monitor with HemoSphere ClearSight Module

The HemoSphere advanced monitor when used with the HemoSphere ClearSight module, pressure controller or Smart Pressure Controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the noninvasive system is indicated for use in patients with comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient’s likelihood of future hypotensive events 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.

Indication for Acumen IQ Plus and VitaWave Plus finger cuffs:

The Acumen IQ Plus and VitaWave Plus finger cuff adult indicated for patients over 18 years of age to continuously blood pressure and associated hemodynamic parameters when used with a compatible Edwards monitoring platform.

Smart Pressure Controller:

The Smart Pressure Controller is intended for use with an Edwards compatible noninvasive monitoring system - composed of compatible monitor, pressure source (pump), compatible Edwards finger cuff(s) and pressure controller - for continuous noninvasive measurement of blood pressure and associated hemodynamic parameters.
Refer to the operator's manual of the compatible Edwards monitor being used for specific information on the intended use environment and patient population.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – HemoSphere 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: (213) 479-4688

Date Prepared: July 22, 2025

II. Device Information:

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

Trade Name:
HemoSphere Advanced Monitor- HEM1
HemoSphere Vita Monitor- HEMVITA1
HemoSphere ClearSight Module- HEMCSM10
HemoSphere VitaWave Module- HEMVWM1
HemoSphere Technology Module- HEMTOM10
HemoSphere Vita Technology Module- HEMVTOM1
HemoSphere Pressure Cable- HEMPSC100
Smart Pressure Controller- PC1Q
Acumen IQ Plus Finger cuff- AIQCA2
VitaWave Plus Finger cuff- VWCA2

Common Name: Programmable Diagnostic Computer, Fiber Optic Oximeter Catheter, Adjunctive predictive Cardiovascular Indicator, Medium-Term Adjunctive Predictive Cardiovascular Indicator, Adjunctive Open Loop Fluid Therapy Recommender, and Noninvasive blood pressure measurement system

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

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

III. Predicate Device

Primary Predicate Device:

- HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K223865, cleared June 9th, 2023. It is the base device on which the various hardware and 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, new configuration Pressure controller (PC1Q).

Additional Predicate Devices:

- HemoSphere Alta Advanced Monitoring Platform (K242451, Cleared Dec 9th, 2024) is being utilized as a secondary predicate for Fluid Meter Only Mode, modification to provide an option to use the existing pulse rate instead of heart rate input for calculating associated parameters, and additional miscellaneous GUI updates for user convenience such as HPI Yellow display and Cardiac Power Output (CPO) as a key parameter. It has been utilized for substantial equivalence in terms of the intended use, and graphical user interface (GUI) used.

- Acumen IQ finger cuff (AIQCA) by Edwards Lifesciences, K230919, cleared October 24th, 2023, is being utilized for the Acumen IQ Plus finger cuff (AIQCA2). It has been utilized for substantial equivalence in terms of the indication for use, intended use, and technological characteristics
- Acumen Hypotension Prediction Index (HPI) algorithm by Edwards Lifesciences, K230057, cleared on June 8th, 2023, utilized for the HPI Adjustable MAP (Hypotension threshold) feature.
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IV. Device Description

Device Description: The HemoSphere Advanced Monitor was designed to simplify the customer experience by providing one platform with modular solutions for all hemodynamic monitoring needs. The user can choose from available optional sub-system modules or use multiple sub-system modules at the same time. This modular approach provides the customer with the choice of purchasing and/or using specific monitoring applications based on their needs. Users are not required to have all of the modules installed at the same time for the platform to function.

V. Indications for Use:

HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module

The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) and derived hemodynamic parameters in a hospital environment. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. It may also be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards Swan-Ganz catheter and Swan-Ganz Jr catheter indications for use statements for information on target patient population specific to the catheter being used. Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

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HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

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

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

HemoSphere Advanced Monitor with HemoSphere Pressure Cable

The HemoSphere advanced monitor when used with the HemoSphere pressure cable is indicated for use in 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 Edwards 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 Edwards 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 Acumen Hypotension Prediction Index (HPI) parameter.

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

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

The Acumen Assisted Fluid Management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response

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to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the Assisted Fluid Management suggestions.

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

HemoSphere Advanced Monitor with HemoSphere Technology Module and ForeSight Oximeter Cable

The non-invasive ForeSight oximeter cable is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no flow ischemic states. The ForeSight Oximeter Cable is also intended to monitor relative changes of total hemoglobin of blood under the sensors. The ForeSight Oximeter Cable is intended to allow for the display of StO2 and relative change in total hemoglobin on the HemoSphere advanced monitor.

- When used with large sensors, the ForeSight Oximeter Cable is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with medium sensors, the ForeSight Oximeter Cable is indicated for use on pediatric subjects ≥3 kg.
- When used with small sensors, the ForeSight Oximeter Cable is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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

HemoSphere Advanced Monitor with HemoSphere ClearSight Module

The HemoSphere advanced monitor when used with the HemoSphere ClearSight module, pressure controller or Smart Pressure Controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the

noninvasive system is indicated for use in patients with comorbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events 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.

Indication for Acumen IQ Plus and VitaWave Plus finger cuffs:

The Acumen IQ Plus and VitaWave Plus finger cuff adult indicated for patients over 18 years of age to continuously blood pressure and associated hemodynamic parameters when used with a compatible Edwards monitoring platform.

Smart Pressure Controller:

The Smart Pressure Controller is intended for use with an Edwards compatible noninvasive monitoring system - composed of compatible monitor, pressure source (pump), compatible Edwards finger cuff(s) and pressure controller - for continuous noninvasive measurement of blood pressure and associated hemodynamic parameters.
Refer to the operator's manual of the compatible Edwards monitor being used for specific information on the intended use environment and patient population.

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Intended Use: The HemoSphere advanced monitoring platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

The Viewfinder remote mobile application can be used for supplemental near real-time remote display of monitored hemodynamic parameter data as well as faults, alerts and notifications generated by the HemoSphere advanced monitoring platform.

The HemoSphere advanced monitoring platform is intended for use with compatible Edwards Swan-Ganz and oximetry catheters, Swan-Ganz Jr catheters, FloTrac sensors, FloTrac Jr sensors, Acumen IQ sensors, TruWave disposable pressure transducers, ForeSight/ForeSight Jr sensors, Acumen IQ fluid meter, and ClearSight/ClearSight Jr/Acumen IQ/Acumen IQ Plus/VitaWave/VitaWave Plus finger cuffs

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

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
CO	continuous cardiac output	HemoSphere Swan-Ganz module	Adult only	Operating Room, Intensive Care Unit, Emergency Room
sCO	STAT cardiac output			
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			

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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 advanced monitor and a connected HemoSphere oximetry cable are listed below:

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
SvO2	Mixed Venous Oxygen Saturation	HemoSphere oximetry cable	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
ScvO2	Central Venous Oxygen Saturation			

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere advanced monitor and both a connected HemoSphere Swan-Ganz module and oximetry cable are listed below:

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
DO2	Oxygen Delivery	HemoSphere Swan-Ganz module and HemoSphere oximetry cable	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			

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

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
CO20s	20-second cardiac output	HemoSphere Swan-Ganz module and	Adult only	Operating room, intensive care unit, emergency room
CI20s	20-second cardiac index			
SV20s	20-second stroke volume			

SVI20s	20-second stroke volume index	HemoSphere pressure cable		
[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.				

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

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
CO	Continuous Cardiac Output[1]	HemoSphere pressure cable	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}	Systolic Blood Pressure			
CVP	Central Venous Pressure		Adult only	
DIA_{PAP}	pulmonary artery diastolic blood pressure			
dP/dt	Systolic slope[2]			
Ea_{dyn}	Dynamic Arterial Elastance[2]			
HPI	Acumen Hypotension Prediction Index			
MPAP	Mean Pulmonary Arterial Pressure			
SYS_{PAP}	Systolic pulmonary artery blood pressure			
[1]FloTrac parameters are available when using a FloTrac/Acumen IQ sensor and if the FloTrac feature is enabled. *[2]HPI parameters are available when using an Acumen IQ sensor and if the HPI feature is activated.*				

A list of Acumen Assisted Fluid Management (AFM) outputs available for surgical patients ≥18 years of age while monitoring with the HemoSphere advanced monitor and a connected HemoSphere pressure cable are listed below:

AFM output	Sub-system technology used	Patient Population	Hospital Environment
Fluid Bolus Suggested			

Test Bolus Suggested	HemoSphere pressure cable	≥18 years of age only	Operating room
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 advanced monitor and both a connected HemoSphere pressure cable and oximetry cable are listed below:

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
DO_2	Oxygen Delivery	HemoSphere pressure cable and HemoSphere oximetry cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
DO_2I	Oxygen Delivery Indexed			
VO_2	Oxygen Consumption			
VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored			
VO_2I	Oxygen Consumption Index			
VO_2Ie	Estimated Oxygen Consumption Index when $ScvO_2$ is being monitored			

Tissue oxygen saturation, StO2, can be monitored with the HemoSphere advanced monitor, a connected HemoSphere technology module, and the ForeSight oximeter cable as listed below.

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
StO_2	Tissue oxygen saturation	ForeSight oximeter cable and HemoSphere technology module	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
ΔctHb	relative change in total hemoglobin			

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere ClearSight module are listed below:

Parameter	Description	Sub-system technology used	Patient Population	Hospital Environment
CO	Continuous Cardiac Output	HemoSphere	Adult and	Operating

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CPO	Cardiac Power Output	ClearSight module	pediatric ≥ 12	Room, Intensive Care Unit, Emergency Room
CI	Continuous Cardiac Index			
DIA_{ART}	arterial diastolic blood pressure			
SYS_{ART}	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 PredictionIndex[1]			

[1]HPI parameters are available when using an Acumen IQ or Acumen IQ Plus finger cuff and heart reference sensor (HRS), if applicable, and if the HPI feature is activated. Activation is only available in certain areas. Please contact your local Edwards representative for more information on enabling this advanced feature.
NOTE: CO/CI and SV/SVI are measured using a reconstructed brachial arterial waveform. All other monitored parameters use a reconstructed radial arterial waveform. SVR/SVRI are derived from CO/CI and MAP along with an entered or monitored CVP value.

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

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

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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 (K223865, cleared June 9th, 2023). Additionally, the updated hardware configurations for the components: Acumen IQ Plus finger cuff and Smart Pressure Controller remain similar 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 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.

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

- Hardware: The subject device includes new hardware configuration of the Pressure Controller and finger cuff: Acumen IQ/VitaWave Plus finger cuff and Smart Pressure Controller. The updated configuration includes modifications to provide correction for the hydrostatic height difference between the finger and heart.

- Software: The subject device includes updated software to support the new features.

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

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

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Software modifications to the subject HemoSphere Advanced Monitoring Platform (K223865, Cleared June 9th, 2023):

- Software modification to the HemoSphere Advanced Monitor (HEM1): The existing software components of HemoSphere Advanced Monitor (HEM1-SHM and DBM) have been updated to support graphical user interface (GUI) associated with the new features introduced to the HemoSphere Advanced Monitoring Platform.

  The GUI updates include the following features:

- Fluid meter only Mode: 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 provide an option to use the existing pulse rate instead of heart rate input for calculating associated parameters: The HemoSphere 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 have the option to use HR or alternatively utilize existing pulse rate (PR)for the parameter calculation.

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

- Integration of the existing Acumen Hypotension Prediction Index (HPI) Algorithm: The previously cleared HPI Adjustable MAP target algorithm that was cleared in K230057 on June 8, 2023, is being integrated to the HemoSphere Advanced Monitoring Platform. There are no changes to the Acumen HPI algorithm from what was cleared in K230057. The same feature is now integrated

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under the name “Hypotension threshold” into the HemoSphere Advanced Monitoring Platform.

The existing HemoSphere Pressure Cable (HEMPSC100) and HemoSphere ClearSight Module (HEMCSM10) software have been updated to support integration of the HPI Adjustable MAP target algorithm.

- Software modification to the HemoSphere ClearSight/VitaWave Module (HEMCSM10/HEMVWM1): The existing HemoSphere ClearSight Module software has been updated to support a new configuration of the Pressure Controller.

Hardware modifications to the subject HemoSphere Advanced Monitoring Platform (original K223865, Cleared June 9th, 2023):

- Smart Pressure Controller: A new hardware configuration of the existing accessory, Pressure controller (PC2/HEMPC2) most recently cleared in K223865, is being introduced to provide correction for the hydrostatic height difference between the finger and heart under the tradename “Smart Pressure Controller” (Model- PC1Q).

Hardware modifications to the subject Acumen IQ finger cuff, Model: AIQCA (K230919, Cleared October 24th, 2023):

- Acumen IQ Plus finger cuff (AIQCA2): A new configuration of the Acumen IQ finger cuff is being introduced to provide continuous noninvasive measurement of blood pressure and hemodynamic monitoring under the tradename of Acumen IQ Plus finger cuff (AIQCA2) and VitaWave Plus finger cuff (VWCA2).

Labelling Modifications to the HemoSphere Advanced Monitoring Platform and Acumen IQ finger Cuff to address the device modifications

New labelling is being created for the updated Intended use and Indications for use for Acumen IQ/VitaWave Plus finger cuff.

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- 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 the Adjustable MAP targets and patient population to include non-surgical patients during non-invasive monitoring cleared in K230057 on June 8, 2023.

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 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, HemoSphere Vita Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere Technology Module, ForeSight Oximeter Cable, ClearSight Module, VitaWave Module, Pressure Controller, Heart Reference Sensor, Acumen AFM Cable, and Smart Pressure Controller. 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 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". All tests passed.

Conclusion

The technological characteristics of the subject and predicate devices are identical. The HemoSphere 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 Advanced Monitoring Platform is substantially equivalent to the legally marketed predicates.