FDA U.S. FOOD & DRUG ADMINISTRATION

July 8, 2021

Edwards Lfesciences
Chirag Shah
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K211465
    Trade/Device Name: HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere
                Oximetry Cable, HemoSphere Pressure Cable, HemoSphere Tissue Oximetry
                Module, HemoSphere ForeSight Module, HemoSphere ClearSight Module,
                Acumen Hypotension Prediction Index Feature, Viewfinder Remote
    Regulation Number: 21 CFR 870.1425
    Regulation Name: Programmable Diagnostic Computer
    Regulatory Class: Class II
    Product Code: DQK, DQE, QAQ, MUD, DXN, DSB
    Dated: May 10, 2021
    Received: May 11, 2021

Dear Chirag Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced
above and have determined the device is substantially equivalent (for the indications for use stated in the
enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the
enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance
with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a
premarket approval application (PMA). You may, therefore, market the device, subject to the general
controls provisions of the Act. Although this letter refers to your product as a device, please be aware that
some cleared products may instead be combination products. The 510(k) Premarket Notification Database
located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination
product submissions. The general controls provisions of the Act include requirements for annual registration,
listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and
adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We
remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be
subject to additional controls. Existing major regulations affecting your device can be found in the Code of
Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements
concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*

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Device Name

HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, HemoSphere Tissue Oximetry Module, HemoSphere ForeSight Module, HemoSphere ClearSight Module, Acumen Hypotension Prediction Index, Viewfinder Remote

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. It may also be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

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

HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

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

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

HemoSphere Advanced Monitor with HemoSphere Pressure Cable

The HemoSphere Advanced Monitor when used with the HemoSphere Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac, Acumen IQ and TruWave DPT sensor indications for use statement for information on target patient population specific to the sensor being used.

The Edwards Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Acumen Hypotension Prediction Index (HPI) parameter.

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

HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module and FORE-SIGHT ELITE Tissue Oximeter Module

The non-invasive Fore-Sight Elite tissue oximeter module 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 Fore-Sight Elite tissue oximeter module is intended to allow for the display of StO2 on the HemoSphere advanced monitor.
• When used with large sensors, the Fore-Sight Elite tissue oximeter module is indicated for use on adults and transitional adolescents ≥40 kg.

• When used with medium sensors, the Fore-Sight Elite tissue oximeter module is indicated for   use on pediatric subjects ≥3 kg.

• When used with small sensors, the Fore-Sight Elite tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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

HemoSphere Advanced Monitor with HemoSphere ClearSight Module

The HemoSphere advanced monitor when used with the HemoSphere ClearSight module, pressure controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere advanced monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. Refer to the ClearSight finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – HemoSphere Advanced Monitoring Platform

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Chirag Shah Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 Telephone: (949) 250-1580 Fax: (949) 809-2972
Date:	July 1, 2021
Platform Name	HemoSphere Advanced Monitoring Platform
Trade Name:	HemoSphere Advanced Monitor HemoSphere Swan-Ganz Module HemoSphere Oximetry Cable HemoSphere Pressure Cable HemoSphere Tissue Oximetry Module HemoSphere ForeSight Module HemoSphere ClearSight Module Acumen Hypotension Prediction Index feature Viewfinder Remote
Common Name:	Cardiac Output/Oximetry/Ejection Fraction Computer
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 21 CFR 870.2700 Oximeter, Tissue Saturation 21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive 21 CFR 870.2770 Plethysmograph, Impedance

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Product Code:	DQK, Class II DQE, Class II QAQ, Class II MUD, Class II DSB, Class II DXN, Class II
Primary Predicate Device:	HemoSphere Advanced Monitoring Platform manufactured by Edwards Lifesciences, K201446, cleared October 1, 2020.
Device Description:	The HemoSphere Advanced Monitoring platform was designed to simplify the customer experience by providing one platform with modular solutions for their hemodynamic monitoring needs. The user can choose from the available optional sub-system modules or use multiple sub-system modules at the same time. This modular approach provides the customer with the choice of purchasing and/or using specific monitoring applications based on their needs. Users are not required to have all of the modules installed at the same time for the platform to function.

HemoSphere Advanced Monitoring Platform consists of the HemoSphere Advanced Monitor that provides a means to interact with and visualize hemodynamic and volumetric data on a screen and five (5) optional external modules: the HemoSphere Swan-Ganz Module (K163381 Cleared, April 14, 2017), the HemoSphere Oximetry Cable (K163381 Cleared, April 14, 2017), HemoSphere Pressure Cable (K180881 Cleared, November 16, 2018), HemoSphere Tissue Oximetry Module (K190205 August 29, 2019), HemoSphere ForeSight Module (K180003, May 10, 2018), and the HemoSphere ClearSight Module (K201446 cleared October 1, 2020).

The HemoSphere Advanced Monitor (K201446 most recently cleared October 1, 2020), subject of this submission, is being modified to enable connectivity to a Viewfinder Remote mobile application via a software-based Viewfinder Hub and Viewfinder Cloud.

The Viewfinder Remote mobile application provides clinicians with a supplemental near-real time display of the patient hemodynamic data from the connected HemoSphere Advanced Monitoring Platform. The Viewfinder Remote application is part of the Edwards Viewfinder network, which includes Viewfinder Hub and Viewfinder Cloud. The Viewfinder Remote mobile application functions as a supportive visual aid for patient status communication between clinicians and allows them to view multiple patient monitoring sessions at once from their mobile device. The near-real time updates to patient monitoring sessions includes non-invasive hemodynamic parameter data and the associated physiological alarm notifications, historical trend data and parameter waveform data.

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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. When used in conjunction with a HemoSphere Pressure Cable, CO_{20s}, CI_{20s}, SV_{20s} and SVI_{20s} can be monitored. Use of HemoSphere Swan-Ganz Module in conjunction with HemoSphere Pressure Cable is restricted to adult patients only. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment.

Refer to the Edwards Swan-Ganz catheter indications for use statement for information on target patient population specific to the catheter being used.

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

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

HemoSphere Advanced Monitor with HemoSphere Pressure Cable
The HemoSphere Advanced Monitor when used with the HemoSphere Pressure Cable is indicated for use in critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac, Acumen IQ and TruWave DPT sensor indications for use statement for information on target patient population specific to the sensor being used.

The Edwards Lifesciences Acumen Hypotension Prediction Index feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (defined as mean arterial pressure < 65 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions

should be made based solely on the Hypotension Prediction Index (HPI) parameter.

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

HemoSphere Advanced Monitor with HemoSphere ForeSight Module and HemoSphere Tissue Oximetry Module
The noninvasive FORE-SIGHT ELITE tissue oximeter module 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 FORE-SIGHT ELITE tissue oximeter module is intended to allow for the display of StO_2 on the HemoSphere advanced monitor.

- When used with large sensor is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for use on pediatric subjects ≥3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE tissue oximeter module is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

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

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

Refer to the ClearSight finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

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

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hospital setting. The HemoSphere Advanced Monitoring Platform can be used with the Viewfinder Remote mobile application for supplemental near real-time remote display of tissue oximetry and non-invasive hemodynamic parameter data monitored with a FORE-SIGHT ELITE oximeter module and HemoSphere ClearSight Module, respectively.

The HemoSphere Advanced Monitoring Platform is intended for use with the Edwards Swan-Ganz and Oximetry Catheters and FloTrac, Acumen IQ, TruWave DPT sensors and ClearSight cuffs.

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

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

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
SvO_2	Mixed Venous Oxygen Saturation	HemoSphere Oximetry Cable	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room
$ScvO_2$	Central Venous Oxygen Saturation			

A comprehensive list of additional parameters that are available for adult and pediatric patient populations on the HemoSphere Advanced Monitor and a connected HemoSphere Swan-Ganz Module and a connected HemoSphere Oximetry Cable are as listed below:

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
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 $ScvO_2$ is being monitored			
VO2I	Oxygen Consumption Index			
VO2Ie	Estimated Oxygen Consumption Index when $ScvO_2$ is being monitored			

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO/ CI	Continuous Cardiac Output[1]/ Continuous Cardiac Index[1]	HemoSphere Pressure Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
CVP	Central Venous Pressure			
DIA	Systemic arterial diastolic blood pressure			
DIA_{PAP}	pulmonary artery diastolic blood pressure			
dP/dt	Systolic slope[2]			
Ea_{dyn}	Dynamic Arterial Elastance[2]			
MAP	Mean Arterial Pressure			
MPAP	Mean Pulmonary Arterial Pressure			
PPV	pulse pressure variation[1]			
PRART	Pulse rate			
SV/ SVI	Stroke Volume[1]/ Stroke Volume Index[1]			
SVR/ SVRI	Systemic Vascular Resistance[1]/ Systemic Vascular Resistance[1] Index			
SVV	Stroke Volume Variation[1]			
SYS	Systolic Blood Pressure			
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.

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
DO2	Oxygen Delivery	HemoSphere Swan-Ganz Module and HemoSphere Oximetry Cable	Adult only	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 Module Used	Patient Population	Hospital Environment
CO_{20s}	20-second cardiac output	HemoSphere Swan-Ganz Module and HemoSphere Oximetry Cable	Adult only	Operating Room, Intensive Care Unit, Emergency Room
CI_{20s}	20-second cardiac index			
SV_{20s}	20-second stroke volume			
SVI_{20s}	20-second stroke volume index			

A comprehensive list of parameters available while monitoring with the HemoSphere advanced monitor and a connected HemoSphere Tissue Oximetry Module, and HemoSphere ForeSight Module are listed below.

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
StO_2	Absolute regional hemoglobin oxygen saturation of blood under the sensors	HemoSphere ForeSight Module and HemoSphere Tissue Oximetry Module	Adult and Pediatric	Operating Room, Intensive Care Unit, Emergency Room

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

Parameter	Description	Sub-System Module Used	Patient Population	Hospital Environment
CO/CI	Continuous Cardiac Output/ Continuous Cardiac Index	HemoSphere ClearSight Module	Adult only	Operating Room, Intensive Care Unit, Emergency Room
DIA	noninvasive arterial diastolic blood pressure			
MAP	Noninvasive Mean Arterial Pressure			
PPV	pulse pressure variation			

PR	Noninvasive Pulse rate			
SV/ SVI	Stroke Volume/ Stroke Volume Index			
SVR/ SVRI	Systemic Vascular Resistance Systemic Vascular Resistance Index			
SVV	Stroke Volume Variation			
SYS	Systolic Blood Pressure			

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

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

Intended use – Viewfinder Remote:

Viewfinder Remote is a mobile application which provides supplemental remote near real-time display of non-invasive hemodynamic parameters measured by a connected HemoSphere advanced monitoring platform. Viewfinder Remote allows clinicians to view continuous monitoring data and alarms/alerts remotely for multiple patients. All displayed data is generated by connected HemoSphere advanced monitoring platforms, and not by Viewfinder Remote. Viewfinder Remote is intended for use by clinicians as a supportive visual aid, and not as a replacement for in-person patient monitoring with connected HemoSphere advanced monitoring platforms.

Comparison to Predicate Device:

The existing HemoSphere Advanced Monitoring Platform (K201446, cleared October 1, 2020) consists of:

- HemoSphere Advanced Monitor
- HemoSphere Swan-Ganz Module
- HemoSphere Oximetry Cable
- HemoSphere Pressure Cable
- HemoSphere Tissue Oximetry Module
- HemoSphere ForeSight Module
- HemoSphere ClearSight Module
- Acumen Hypotension Prediction Index feature (when used with Acumen IQ sensor only)

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As part of its connectivity development program, Edwards has modified the HemoSphere Advanced Monitor *(subject of this 510(k))* to allow it to wirelessly stream continuously monitored non-invasive hemodynamic parameter data to the Viewfinder Remote *(subject of this 510(k))*, a mobile device-based application, for remote viewing of the information.

As a connected device, cybersecurity modifications have been implemented on the HemoSphere Advanced Monitor. Additionally, workflow-based updates to support the functionality of remote viewing, including the ability to end a session, provide additional metadata support, as well as multiple setup wizards for initial configuration have been made.
The following predicate is used to establish substantial equivalence:

- Primary Predicate: HemoSphere Advanced Monitor (K201446, cleared October 1, 2020) utilized for substantial equivalence to the HemoSphere Advanced Monitor in terms of the graphical user interface (GUI) used, wireless module incorporated, device modularity and basic device functionality. Modifications are being made to the HemoSphere Advanced Monitor to add the capability for it to remotely connect to the Viewfinder Remote mobile application.

    Per FDA's guidance, *"Medical Device Accessories – Describing Accessories and Classification Pathways"* the remote view application (Viewfinder Remote) is considered an accessory to the HemoSphere Advanced Monitor since it augments the performance of the HemoSphere Advanced Monitor by allowing convenience of use (remote display of noninvasive hemodynamic parameters, alarms and alerts) of the device. Hence, the primary predicate for this application is the HemoSphere Advanced Monitor (K201446, cleared October 1, 2020).

Verification and validation testing were performed to compare the performance and functionality of the HemoSphere Advanced Monitoring Platform to its predicate device. Testing included a side-by-side comparison of the output parameters using a bench test.

Performance Data (Bench and/or Clinical): The following verification activities were performed in support of a substantial equivalence determination for the modifications being made as part of this submission.

System Verification
End-to-end system verification was performed to ensure data integrity and accuracy from the Monitor to the Remote View mobile application. All tests passed.

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Electrical Safety and Electromagnetic Compatibility (EMC)
The HemoSphere Advanced Monitor and all its connected modules/cables were tested to the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366, IEC 60601-2-34 and IEC 60601-2-49. All tests passed.

Wireless Coexistence Testing
ANSI C63.27/D1.0, bench and simulated environment testing were performed on the entire HemoSphere Advanced Monitoring Platform, including all sub-system modules and its interfacing analog inputs and outputs and the wirelessly connected Viewfinder Remote mobile application running on a mobile device. All tests passed.

Software Verification
The HemoSphere Advanced Monitor is considered as software of Major Level of Concern. The Viewfinder Remote mobile application is considered as software of Moderate Level of Concern.

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

Usability Study
A usability study was performed for the HemoSphere Advanced Monitoring Platform and Viewfinder Remote in accordance with FDA's guidance, "Applying Human Factors and Usability Engineering to Medical Devices". All tests Passed.

Clinical Performance
Clinical data was not required for this device or the modifications being made to the device.

Non-Clinical Performance Conclusions:
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.

Conclusions **Overall Conclusion:**
The nonclinical and clinical tests demonstrate that the HemoSphere Advanced Monitor and the Viewfinder Remote mobile application are substantially equivalent to their legally marketed predicates.