October 21, 2025

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

Re: K253034
Trade/Device Name: HemoSphere Stream Module
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DXN
Dated: September 19, 2025
Received: September 22, 2025

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,

Aneesh S. Deoras -S

for

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253034

Please provide the device trade name(s).

HemoSphere Stream Module

Please provide your Indications for Use below.

The HemoSphere Stream™ Module when used with a Smart Pressure Controller (PC1Q) and VitaWave™ Plus Finger Cuff is indicated for use in adult patients to provide continuous, non-invasive arterial pressure waveform output to a compatible multi-parameter patient monitor. The device is designed for use in clinical environments requiring continuous assessment of blood pressure waveform morphology, without the need for an invasive catheter.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary – HemoSphere 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
Date Prepared:	September 15th, 2025 October 16, 2025

II. Device Information:

Device Name	HemoSphere Stream Module
Trade Name:	HemoSphere Stream Module
Common Name:	Noninvasive blood pressure measurement system
Classification Name:	Programmable Diagnostic Computer 21 CFR 870.1425 Noninvasive blood pressure measurement system 21 CFR 870.1130
Product Code and Regulatory Class:	DQK, Class II DXN, Class II

III. Predicate Device

Primary Predicate Device:	HemoSphere ClearSight Module manufactured by Edwards Lifesciences, K243781 cleared July 23rd, 2025.

IV. Device Description

Device Description: The HemoSphere Stream™ Module when used with the Smart Pressure Controller (PC1Q) and VitaWave™ Plus Finger Cuff is indicated for use in adult patients to provide continuous, non-invasive arterial pressure waveform output to a compatible multi-parameter patient monitor.

V. Indications for Use:

The HemoSphere Stream™ Module when used with a Smart Pressure Controller (PC1Q) and VitaWave™ Plus Finger Cuff is indicated for use in adult patients to provide continuous, non-invasive arterial pressure waveform output to a compatible multi-parameter patient monitor. The device is designed for use in clinical environments requiring continuous assessment of blood pressure waveform morphology, without the need for an invasive catheter.

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

Intended Use: The HemoSphere Stream™ Module is intended to be used by qualified personnel or trained professionals in a hospital setting.

The HemoSphere Stream™ Module is intended for use with compatible VitaWave™ Plus Finger Cuffs.

The HemoSphere Stream™ Module is intended to transmit a continuous, non-invasive blood pressure waveform to a compatible patient monitor.

VI. Comparison of Technological Characteristics with the Predicate Devices:

The purpose of this 510(k) submission is to introduce the following modification to the HemoSphere ClearSight Module (Cleared in K243781on July 23rd, 2025):

- Introduction of the HemoSphere Stream Module, a configuration of the HemoSphere ClearSight™ Module to provide limited functionality

  The existing previously cleared HemoSphere ClearSight Module (K243781, cleared July 23, 2025) is intended for use with the Smart Pressure Controller and a compatible Edwards finger cuff to noninvasively measure blood pressure waveform, blood pressure parameters, and associated hemodynamic parameters. The ClearSight

Module acquires the waveform, calculates the parameters, and displays them on the connected monitor.

To make this technology more accessible in a cost-effective manner and support broader patient benefit, Edwards has introduced the HemoSphere Stream Module, which is designed to provide the continuous noninvasive blood pressure waveform to the connected monitor. The HemoSphere Stream Module provides only the continuous blood pressure waveform to the connected monitor and does not calculate or display blood pressure parameters or derived hemodynamic parameters.

Performance Data:

The following verification activities were conducted to assess the modification included in this submission. Pass/fail criteria were based on the specifications cleared for the predicate device, and the results demonstrated substantial equivalence.

Software Verification

Software verification was performed in accordance with FDA's *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. This process included verification of software design, development, and traceability. There were no changes to how the HemoSphere Stream Module acquires and provides continuous blood pressure waveforms compared to the HemoSphere ClearSight Module. The same methods and acceptance criteria as the predicate device (K243781) were applied. All tests passed successfully.

System Verification

System verification confirmed that the HemoSphere Stream Module performs as intended, providing the blood pressure waveform to the connected monitor without introducing any issues that could impact device safety or effectiveness. The same methods and acceptance criteria as the predicate device (K243781) were used. All tests passed successfully.

Conclusions

The technological characteristics of the subject and predicate devices are identical with respect to blood pressure waveform functionality. The HemoSphere Stream Module successfully completed functional and performance testing, including software and system verification. These results confirm that the modification does not adversely affect the device's safety or effectiveness and that the subject device is substantially equivalent to the predicate device.