February 24, 2026

Edwards Lifesciences, LLC.
Kshama Pai
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K253186
Trade/Device Name: HemoSphere Nano Monitor (HSNANO1)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DXN
Dated: January 26, 2026
Received: January 26, 2026

Dear Kshama Pai:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253186

Please provide the device trade name(s).

HemoSphere Nano Monitor (HSNANO1)

Please provide your Indications for Use below.

The HemoSphere Nano™ Monitor when used with a compatible non-invasive finger cuff is indicated for adult patients (≥ 18 years of age) in whom cardiac function parameters need to be evaluated as part of a patient's assessment. The HemoSphere Nano™ Monitor and compatible finger cuffs non-invasively measure blood pressure and associated hemodynamic parameters.

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 Nano Monitor

I. Submitter:

Sponsor:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Kshama Pai Manager, Regulatory Affairs 17200 Laguna Canyon Road, Irvine, CA 92618 kshama.pai@bd.com +1 (949) 628-0467
Date Prepared:	January 23, 2026

II. Device Information:

Platform Name:	HemoSphere Nano Monitoring System		
Trade Name:	HemoSphere Nano Monitor (HSNANO1)		
Common Name:	Computer, diagnostic, programmable Noninvasive blood pressure measurement system		
Classification Name:	DQK	Computer, diagnostic, programmable	21CFR 870.1425
	DXN	System, Measurement, Blood-Pressure, Non-Invasive	21 CFR 870.1130

III. Predicate Device:

Primary Predicate Device:	The HemoSphere Advanced Monitoring Platform (K243781 cleared July 23, 2025) is being utilized as the primary predicate for substantial equivalence to the inherent use and basic device functionality of non-invasive hemodynamic monitoring, the principle of operation of core ClearSight technology, the hemodynamic parameters measured, and compatible finger cuffs. The indications for use relative to non-invasive blood pressure hemodynamic monitoring are also equivalent between the subject device and primary predicate.

IV. Device Description:

Device Description: The HemoSphere Nano Monitor is a hand-held monitoring device that measures the arterial pressure waveform collected from a connected non-invasive finger cuff and displays blood pressure and derived hemodynamic parameters. These parameters are continuously displayed for up to a period of 10 minutes, serving as a series of spot-check or point-in-time measurements. As such, the device does not feature any physiological alarms. It is compatible for use with the single use Acumen IQ Plus finger cuff (AIQCA2; cleared via K243781).

The HemoSphere Nano Monitor utilizes the same principle of operation, algorithms, and mechanism for non-invasive monitoring hemodynamic parameters as the primary predicate, HemoSphere Advanced Monitoring Platform (K243781). When compared to the primary predicate, the subject device introduces a new hardware configuration with a smaller form factor. This new hardware configuration is powered by a rechargeable battery and features a smaller display to enable the product to be hand-held. Contrary to the predicate which incorporates a modular approach, the subject integrates all existing non-invasive technology (i.e., the ClearSight Module and Pressure Controller) into the HemoSphere Nano Monitor body itself to provide a unified and compact solution for non-invasive hemodynamic monitoring.

V. Indications for Use:

Indications for Use: The HemoSphere Nano™ Monitor when used with a compatible non-invasive finger cuff is indicated for adult patients (≥ 18 years of age) in whom cardiac function parameters need to be evaluated as part of a patient assessment. The HemoSphere Nano™ Monitor and compatible finger cuffs noninvasively measure blood pressure and associated hemodynamic parameters.

Intended Use: The HemoSphere Nano™ Monitor is intended to be used in a setting where healthcare is administered by qualified personnel or trained clinicians. The HemoSphere Nano™ Monitor is intended for use with compatible non-invasive finger cuff for noninvasive measurement of blood pressure and associated hemodynamic parameters.

VI. Comparison with predicate device(s):

Comparison of indications	*The HemoSphere Nano Monitor (subject) and HemoSphere Advanced Monitoring Platform (predicate) have the following similarities:* - Subject and predicate have the same intended use, i.e., non-invasive measurement of blood pressure and associated hemodynamic parameters. No new functionality is being added as a result of this submission. - Subject and predicate have the same indications as they are intended for use in adult patients (≥ 18 years of age) in whom cardiac function parameters need to be evaluated for patient assessment. - Both subject and predicate devices are prescription use (Rx) devices that are intended for use by healthcare professionals only.

Comparison of technological characteristics	The ClearSight continuous non-invasive blood pressure monitoring principle based on volume-clamp methodology is the fundamental technological principle for both subject and predicate devices.
	At a high-level, the HemoSphere Nano Monitor (subject) and HemoSphere Advanced Monitoring Platform (predicate) have the following similarities:
	- Subject and predicate have the same principle of operation and technological characteristics relative to non-invasive blood pressure measurement.
	  o The subject utilizes the same existing CNIBP Technology (i.e., same volume-clamp principle of operation and cleared algorithms) to measure arterial blood pressure.
	  o Subject provides the same derived hemodynamic parameters for display as the predicate. No new parameters are being added as a result of this submission. The performance requirements and specifications are equivalent between the subject and predicate device.
	- Subject and predicate both use the same accessories i.e., Acumen IQ Plus finger cuffs.

The HemoSphere Nano Monitor (subject) and HemoSphere Advanced Monitor (predicate) have the following differences:

- The predicate HemoSphere Advanced Monitoring Platform is modular and supports hemodynamic monitoring via invasive, minimally invasive and non-invasive modalities, whereas the subject only utilizes a subset of the overall functionality of the predicate (i.e., non-invasive hemodynamic monitoring).
- The subject has a streamlined GUI for display of CNIBP parameters only (i.e., subset of the GUI features of the predicate).
- The subject has a smaller form factor that integrates the CNIBP machinery (i.e., pump and manifold) into the monitor body to enable the device to be hand-held. This difference in size does not change the overall intended purpose as it does not have an impact on the CNIBP functionality or the associated performance specifications. Testing was performed to show the same performance specifications are met.
- Unlike the predicate which is intended for short-term continuous hemodynamic monitoring with alarms, the real-time data available on the subject is meant for transient use and spot-checking without physiological alarms in healthcare settings. These differences do not change the overall intended purpose as both have the purpose of non-invasive blood pressure monitoring. Additionally, both the subject and predicate devices are prescription use (Rx) devices that are intended for use by healthcare professionals only.

VII. Performance Data and Conclusion:

Performance Data (Bench and/or Clinical):

The following verification and validation activities were performed in support of a substantial equivalence determination for the subject HemoSphere Nano Monitor (new hardware configuration) to the predicate devices and to ensure the safety and effectiveness of the HemoSphere Nano Monitor.

System Verification (Non-clinical performance)

Completion of all verification and validation activities demonstrated that the subject device and its software meet their predetermined design and performance specifications. Verification activities performed confirmed that the differences in design, specifications, and materials do not adversely affect the safety and effectiveness of the subject device.

Mechanical, electrical, and system integration testing were successfully conducted to ensure the device met its requirements and to verify the safety and effectiveness of the device. System integration testing also ensured that the subject HemoSphere Nano Monitor functions as intended when

connected to the Acumen IQ Plus finger cuffs. Bench testing was performed to verify the pneumatic pressure accuracy requirements pertaining to ClearSight technology were met and that the embedded algorithms were reliably translated and integrated. Measured and derived parameters were tested using a bench simulation and volunteer/participant data. All tests passed.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the subject HemoSphere Nano Monitoring Platform, consisting of the HemoSphere Nano Monitor and the Acumen IQ Plus 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, IEC 60601-2-57, and ISO 81060-2. All tests passed.

Software Verification
Software verification was performed per IEC 62304 and FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued June 14, 2023), and *General Principles of Software Validation* (issued January 11, 2002). The HemoSphere Nano software was tested at a sub-system level to ensure the safety of the device. All tests passed.

Cybersecurity requirements and documentation for the HemoSphere Nano monitoring system were developed and assessed at system level in accordance with FDA's Guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued June 27, 2025). All cybersecurity risks were mitigated to an acceptable risk level based on the risk assessment.

Usability Study
A Usability study was conducted per IEC 62366 and FDA's guidance document, *Applying Human Factors and Usability Engineering to Medical Devices* (issued February 3, 3016), to investigate primary operating functions and critical tasks of the system for any usability issues that may lead to patient or user harm. The successful results provide objective evidence that the system is safe and effective with respect to the intended users, uses, and use environments.

Conclusions

Overall Conclusion:
The subject HemoSphere Nano Monitor has successfully passed functional and performance testing, including validation, software verification and validation, bench, and usability testing. Completion of all performance verification and validation activities demonstrated that the subject device meets their predetermined design and performance specifications. Verification activities performed confirmed that the

differences in the features and design do not raise different questions of safety and effectiveness. The testing performed demonstrates that the HemoSphere Nano Monitor is substantially equivalent to its legally marketed predicate device.