June 16, 2026

80 Beats Medical GmbH
% Marcella Garcia
Regulatory Consultant
Marcella Garcia
249 Fox Hill Rd.
Burlington, Massachusetts 01803

Re: K260693
Trade/Device Name: VicorderCS (VCS-SYS-1100)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 21, 2026
Received: May 21, 2026

Dear Marcella Garcia:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,
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Office of Cardiovascular Devices
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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)*
K260693

Device Name
VicorderCS (VCS-SYS-1100)

Indications for Use *(Describe)*
VicorderCS is intended for the non-invasive measurement of blood pressure and pulse rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (8 in to 17 in). VicorderCS is not intended for use in patients with severe arrhythmias, including atrial fibrillation.

The device is intended for use by trained medical personnel in clinical settings.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #:

510(k) Summary

Prepared on: 2026-05-21

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Ms. Marcella Garcia
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VicorderCS (VCS-SYS-1100)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K113185	Omron HBP-1300	DXN

Device Description Summary

21 CFR 807.92(a)(4)

- Device identity and Intended Use:
The VICORDER Cardiovascular Diagnostic System (VicorderCS) is a non-invasive, automated oscillometric sphygmomanometer intended to measure systolic and diastolic blood pressure and pulse rate in adult patients with upper-arm circumference 22-42cm. The device is not intended for use in patients with severe arrhythmias, including atrial fibrillation, or pregnant patients. The device is intended for use by trained medical personnel in clinical settings.
- System components and configuration:
The system comprises: (a) the Vascular Sensor unit housing the pressure generation/measurement hardware and a touch display used to run examinations and present results; (b) the Data Station mini-computer that stores patient/examination data and provides a browser-based user interface on the local network; and (c) blood-pressure cuffs (patient-applied parts) connected via pressure hoses.
- Principle of operation:
Blood pressure is determined by an oscillometric method using controlled linear inflation and deflation. The device acquires cuff

pressure waveforms and estimates systolic/diastolic values; pulse rate is derived concurrently. The device employs both inflation and deflation phases to optimize accuracy, and provides on-screen guidance and status.
Examinations and data handling follow a workflow with authenticated access and upload/storage to the Data Station over a local network.
- Physical and performance characteristics:
Pressure system range 0-300mmHg; display accuracy ±3mmHg; NIBP ranges: systolic 60-250mmHg, diastolic 40-200mmHg; nominal bleed rate ~3mmHg/s; mean error ≤±5mmHg, SD ≤8mmHg.
Operating environment 5-40°C, 15-90% RH (non-condensing); ingress protection IP21; Type BF applied parts; Class II protection; EMC emissions CISPR11 Group1/ClassB.
Patient-applied parts (cuffs): polyurethane outer surfaces; available sizes cover 22-42cm arms.
Power: Supplied per external off-the-shelf medical-grade power supplies (5VDC, 4A).
- Clinical limitations:
Not indicated for neonates/children/pregnant patients; MR unsafe; not for use with HF electrosurgery or defibrillators.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

VicorderCS is intended for the non-invasive measurement of blood pressure and pulse rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (8 in to 17 in). VicorderCS is not intended for use in patients with severe arrhythmias, including atrial fibrillation.
The device is intended for use by trained medical personnel in clinical settings.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The predicate is indicated for adult and pediatric patients with arm circumference 12 to 50 cm, whereas the subject device is indicated for adults only with arm circumference 22 to 42 cm. These differences represent a narrower patient population and cuff-fit range, but do not change the device's intended use, which remains the non-invasive measurement of blood pressure and pulse rate.

Technological Comparison

21 CFR 807.92(a)(6)

The VicorderCS and the legally marketed Omron HBP-1300 device share the same fundamental non-invasive, upper-arm, oscillometric technology for determining blood pressure and pulse rate. Both have equivalent performance and accuracy consistent with applicable consensus standards. Both systems are classified as Class II medical electrical equipment with Type BF applied parts, and conform to the same base safety and performance standards, including IEC 60601-1, IEC 60601-1-2, IEC 80601-2-30, and ISO 81060-2.

Differences are limited to the following implementation details: VicorderCS acquires during inflation and deflation while the HBP-1300 uses deflation with an optional manual mode. VicorderCS is adult-only with arm circumference 22-42 cm, whereas the predicate includes pediatric patients and a 12-50 cm range. The predicate features an optional battery; VicorderCS adds an optional data-management unit that does not alter the measurement method or performance.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical performance testing focused on the verification of the oscillometric blood pressure algorithm and the pneumatic subsystem functionality. Algorithmic performance was verified using a calibrated NIBP simulator to ensure systolic, diastolic, and heart rate calculations remained within specified tolerances compared to a reference fixture. Verification testing also included a direct comparison with the predicate NIBP device to support a determination of substantial equivalence. The pneumatic subsystem was tested to confirm accurate pressure control and the successful execution of automated deflation safety features. Verification of system accessories confirmed compatibility with off-the-shelf blood pressure cuffs and the use of bayonet-style connectors. Iterative formative usability evaluations were conducted to assess the user interface and hardware interactions.
Performance requirements for the automated sphygmomanometer followed the ISO 81060-2 standard. Usability engineering was performed in accordance with IEC 62366-1 and the FDA Guidance on Applying Human Factors and Usability Engineering to Medical Devices. Compliance for limb cuff connectors was evaluated against the associated FDA guidance on small-bore connectors.

The substantial equivalence of the VicorderCS NIBP technology is supported through a clinical investigation that was conducted in accordance with ISO 81060-2:2018 (intermittent automated measurement type sphygmomanometers), the same standard the predicate was validated with (2013 revision). The reference method utilized was the auscultatory method performed by two trained human observers using a double stethoscope.
Clinical data collection was performed in Summit County, Colorado, USA.
A total of 86 unique subjects were enrolled and completed the study protocol. The study population fulfilled ISO 81060-2 requirements for participant distribution in terms of gender, age, arm circumference, and systolic/diastolic blood pressure.
The device effectiveness was determined based on the accuracy criteria defined in ISO 81060-2. Criterion 1 assesses the mean and standard deviation of the individual measurement differences between the device under test and the reference. Criterion 2 assesses the SD of the subject-level mean errors. The study successfully met the primary effectiveness endpoints for both systolic and diastolic blood

pressure.
Safety was monitored through Institutional Review Board and adherence to Good Clinical Practice. No adverse events, device-related complications, or unanticipated problems involving risks to subjects were reported during the clinical investigation.
Conclusion: The clinical testing demonstrates that the VicorderCS device meets the performance and accuracy requirements of ISO 81060-2:2018/Amd.1:2020, supporting its effectiveness and substantial equivalence for NIBP measurement.

The nonclinical and clinical testing program demonstrates that the VicorderCS is substantially equivalent to the predicate device (HBP-1300) in terms of safety, effectiveness, and overall performance. Clinical validation performed in accordance with ISO 81060-2 provides evidence that the device meets all specified accuracy requirements for the determination of systolic and diastolic blood pressure. Independent statistical analysis confirms that the device satisfies both Criterion 1 and Criterion 2 of the consensus standard, ensuring clinical performance equivalent to the predicate. Nonclinical bench testing verified the integrity of the pneumatic subsystem and the accuracy of the oscillometric algorithm when evaluated against a calibrated NIBP simulator. Direct comparative testing between the subject and predicate devices further supports the conclusion that the measurement technology performs with equivalent precision across the entire indicated range. The implementation of a dual-phase signal acquisition method enhances measurement robustness, and the added data management unit supports the operator by providing centralized patient management, while maintaining a safety profile identical to the legally marketed predicate. Consequently, the results of the performance testing program conclude that the VicorderCS is as safe and as effective as the Omron device for its intended clinical use.