



July 30, 2025

Cardio Ring Technologies, Inc. Taiwan Branch
% Alexia Haralambous
Senior Principal
Rqm+
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K244007

Trade/Device Name: ArteVu
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: July 1, 2025
Received: July 1, 2025

Dear Alexia Haralambous:

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

510(k) Number (if known)

K244007

Device Name

ArteVu

Indications for Use (Describe)

ArteVu is intended to noninvasively and continuously measure a patient's blood pressure and pulse rate, which are derived from the pulse pressure waveform using the scientific method of pulse waveform decomposition, for use on adult patients aged between 50 and 86 years who are resting in a supine or similarly reclined position.

ArteVu is calibrated using an ISO 81060-2 compliant sphygmomanometer. All parameters derived by ArteVu are shown on a compatible remote display monitor (RDDS) via wired transmission. The device is intended for use by clinicians or other properly trained medical personnel in professional healthcare facilities.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ArteVu
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
K163255	CareTaker4 Physiological Monitor	DXN

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

ArteVu is an automatic, continuous, and non-invasive blood pressure (CNBP) monitoring system designed for adult patients at rest and intended for use by medical professionals. The device features a disposable Finger Clip containing a tactile sensor that detects pulse pressure waveforms at the fingertip. ArteVu utilizes the scientific method of pulse waveform decomposition to derive blood pressure and pulse rate, with initial calibration performed using a non-invasive upper arm cuff. These measurements are displayed on a compatible remote monitor, updated every two seconds via wired transmission. ArteVu also incorporates technical and physiological alarms to enhance reliability, providing continuous and accurate monitoring while alerting users to abnormal conditions.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

ArteVu is intended to noninvasively and continuously measure a patient's blood pressure and pulse rate, which are derived from the pulse pressure waveform using the scientific method of pulse waveform decomposition, for use on adult patients aged between 50 and

86 years who are resting in a supine or similarly reclined position.

ArteVu is calibrated using an ISO 81060-2 compliant sphygmomanometer. All parameters derived by ArteVu are shown on a compatible remote display monitor (RDDS) via wired transmission. The device is intended for use by clinicians or other properly trained medical personnel in professional healthcare facilities.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject ArteVu device has the same intended use as the predicate CareTaker4 System (K163255). They are both intended to noninvasively and continuously measure a patient's blood pressure and pulse rate, which are derived from the pulse pressure waveform using the scientific method of pulse waveform decomposition for use on adult patients at rest. Both devices include calibration, analysis, display, and alarms and are intended for use by clinicians or other properly trained medical personnel.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject ArteVu device is similar to the predicate CareTaker4 device. Both devices utilize an analysis of pulse decomposition derived from piezoresistive inputs to quantify key hemodynamic parameters, including blood pressure. Both are calibrated using an ISO 81060-2 compliant blood pressure device, and all parameters are displayed on a monitor via wired transmission. The blood pressure and pulse measurement ranges are similar between the two devices. Both devices are intended for continuous monitoring and consist of a finger-contact mechanism. However, CareTaker4 uses an oscillometric cuff on a digit, which requires constant coupling pressure. In contrast, ArteVu uses a Finger Clip with a tactile sensor, which only requires the clip to be securely and comfortably placed on the digit without applying additional pressure. This design minimizes the risk of occluding blood flow to the monitored digit during extended use, as it does not require more pressure than necessary to keep the Finger Clip in place. Additionally, while the CareTaker4 does not contain any electrical components in the finger cuff, ArteVu incorporates passive electronic components inside the Finger Clip.

The different technological characteristics of the subject ArteVu system do not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

To establish substantial equivalence to the CareTaker4, ArteVu adheres to the same nonclinical testing standards and meets all the essential performance requirements outlined in those standards. The test results demonstrate that ArteVu and CareTaker4 exhibit comparable levels of safety and effectiveness, ensuring compliance with regulatory benchmarks. Please refer to the eSTAR attachment titled "12.1_Bench Testing Summary" for additional information.

ArteVu's safety and effectiveness have been validated through a clinical study conducted in Taiwan involving 109 subjects. To establish substantial equivalence to the predicate device, CareTaker4, the study design adhered to the acceptance criteria of ISO 81060-2, which was also utilized in the clinical evaluation of CareTaker4. Moreover, to ensure compliance with state-of-the-art standards, the clinical study incorporated elements from IEEE 1708, ISO 81060-3, ISO 80601-2-61, and IEC 60601-2-27.

The study population included subjects recruited from operating rooms and intensive care units. The clinical data demonstrated that ArteVu achieves comparable safety and effectiveness to CareTaker4, supporting the determination of substantial equivalence.

Based on the results of the nonclinical and clinical tests, ArteVu has been demonstrated to be as safe, as effective, and to perform as well as or better than the predicate device, CareTaker4. The nonclinical tests, conducted in accordance with FDA-recognized consensus standards such as ISO 10993, IEC 60601-1, and IEC 60601-1-2, confirmed ArteVu's compliance with essential performance and safety requirements.

The clinical study, conducted with 109 subjects, further validated ArteVu's safety and effectiveness. The study adhered to ISO 81060-2 standards for substantial equivalence evaluation and incorporated elements of IEEE 1708, ISO 81060-3, ISO 80601-2-61, and IEC 60601-2-27, ensuring compliance with state-of-the-art guidelines. The study demonstrated that ArteVu achieves comparable levels of safety and effectiveness to the predicate device, CareTaker4, with adverse effects reported being unrelated to the device or study interventions.

In conclusion, the cumulative evidence supports the determination that the performance of ArteVu is substantially equivalent to the legally marketed CareTaker4 device in terms of safety and effectiveness.