February 13, 2026

Retia Medical Systems, Inc.
Alexander Markovic
VP of Engineering
333 Westchestaer Ave
Suite 102W
White Plains, New York 10604

Re: K253092
Trade/Device Name: Argos Infinity (Rev. 1.0)
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: September 19, 2025
Received: September 23, 2025

Dear Alexander Markovic:

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 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253092

Device Name
Argos Infinity

Indications for Use *(Describe)*

Argos Infinity is intended for use in adult patients (18 years and older). It is designed to provide clinicians with continuous hemodynamic monitoring, including cardiac output and derived parameters, for patients who receive radial arterial blood pressure catheters

The Argos Infinity software is used for the continuous measurement of cardiac output from an intravascular radial arterial blood pressure signal. This signal is derived from a blood pressure signal transmitted over a computer network from a vital signs monitor. The device is intended to be used by clinicians at the bedside or in remote settings to assess advanced hemodynamics of patients in an operating room or in an intensive care unit.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

1. Submitter

Applicant Name: Retia Medical Systems, Inc.

Applicant Address: 333 Westchester Ave Suite 102W White Plains NY 10604 United States

Applicant Contact Telephone: 610 202 9774

Applicant Contact: Alexander Markovic

Applicant Contact Email: amarkovic@retiamedical.com

Date Prepared: Feb 12, 2026

2. Device

Device Trade Name	Argos Infinity
Common Name:	Argos Infinity
Classification Name:	Computer, Diagnostic, Pre-Programmed, Single-Function
Regulation Number:	21 CFR 870.1435
Product Code:	DXG

3. Legally Marketed Predicate Device

Predicate Name and 510(k) Number:

Predicate #: K181372

Predicate Trade Name: Argos

Product Code: DXG

4. Device Description Summary

The proposed “Argos Infinity,” (AI) is a “Software as a Medical Device” (SaMD) designed to calculate the hemodynamic status of a patient from their invasive blood pressure signal. The blood pressure signal is obtained from a digitized waveform source such as a data aggregator used for central waveform viewing in an intensive care unit or an operating room, or a monitoring device. The SaMD has an application programming interface that allows a digital waveform source to send 20 seconds of waveform data and obtain calculated hemodynamic data results for that data segment including cardiac output (CO), stroke volume (SV), systemic vascular resistance (SVR) and their respective indices (normalized to body surface area). In addition, pulse pressure variation is also calculated.

These results are pulled from the SaMD by a third party client application and appended to the patient's online medical record. The SaMD is to be deployed on a network server within the hospital's IT department that is accessible to a client application that can access the same hospital network.

Argos Infinity was clinically validated using bedside patient monitors configured to transmit invasive arterial blood pressure data via a data aggregation system, consistent with the Argos Infinity data acquisition configuration. The monitors included in clinical validation were Philips IntelliVue® patient monitors and GE CARESCAPE® patient monitors, each with invasive blood pressure monitoring capability. These monitors and acquisition configurations represent the complete set of systems included in the Argos Infinity clinical validation testing. Compatibility claims are limited to the validated configurations described above.

The Argos Infinity algorithm is identical to the algorithm implemented in the previously cleared Argos device, with no changes to the signal processing, calculation methods, or performance characteristics. The differences between Argos Infinity and the predicate device are limited to the intended operating environment and deployment model. Argos Infinity is designed for use within a hospital network and supports remote and centralized (command center) monitoring in addition to bedside use, without altering the underlying algorithm or its clinical performance.

5. Indications for Use

Argos Infinity is intended for use in adult patients (18 years and older). It is designed to provide clinicians with continuous hemodynamic monitoring, including cardiac output and derived parameters, for patients who receive radial arterial blood pressure catheters

6. Intended Use

The Argos Infinity software is used for the continuous measurement of cardiac output from an intravascular radial arterial blood pressure signal. This signal is derived from a blood pressure signal transmitted over a computer network from a vital signs monitor. The device is intended to be used by clinicians at the bedside or in remote settings to assess advanced hemodynamics of patients in an operating room or in an intensive care unit.

7. Indications for Use Comparison & Technological Comparison

The device has the identical intended use and similar indications for use as the Argos Monitor. The Argos Infinity includes a clarification to state "patients who receive radial arterial blood pressure catheters". This change does not impact the usage, intended use,

patient population, or user population, as the intended use also states the use of an intravascular radial arterial blood pressure signal. Therefore, the intended use of the Argos Infinity can be considered substantially equivalent.

The technological characteristics of the Argos Infinity are similar to the Argos Monitor (K181372). The algorithm for calculating the hemodynamic status in the Argos Infinity is identical to the Argos Monitor. The differences between the subject and predicate are limited to the implementation of the algorithm. The Argos Infinity is SaMD and has been validated to ensure performance equivalency, including data transmission, to the predicate Argos Monitor. Additionally, the subject Argos Infinity UI has a multipatient view as well as a single patient view. Usability testing has demonstrated that this additional view can be used safely and effectively. No new types of safety or effectiveness questions have been raised and the subject Argos Infinity can be considered substantially equivalent to the predicate Argos Monitor.

8. Non-Clinical and/or Clinical Tests Summary (Performance Data)

Data accuracy and latency testing was performed on the subject and predicate Argos Cardiac Output Monitor devices. The results of the testing demonstrated the substantial equivalence of the subject Argos Infinity's performance.

A clinical comparison between the subject Argos Infinity and the predicate Argos monitor was performed to assess the equivalency of accuracy, precision, trending ability, and reproducibility. The results of testing demonstrated that the subject Argos Infinity is substantially equivalent to the predicate Argos monitor

Based on the results of the performance testing for data accuracy and latency, the subject Argos Infinity can be expected to be at least as safe and effective and to perform at least as well as the predicate Argos Cardiac Output Monitor.

Argos Infinity was assessed and/or tested for and met the following standard requirements:

1. ISO 14971
2. ISO 62366
3. IEC 62304
4. IEC 82304
5. IEC 81001
6. IEC 60601-1-8

Using archived data from 40 OR and ICU patients spanning a wide hemodynamic range, cardiac output results from the Argos Infinity SaMD were compared to those from the FDA-cleared Argos Monitor using identical input recordings. Agreement was assessed against

pre-specified substantial equivalence criteria of ≤0.1 L/min or 6%. Across all analyses and subgroups, Argos Infinity met the substantial equivalence criteria with negligible bias and narrow limits of agreement. Independent comparison of both implementations to pulmonary artery catheter thermodilution demonstrated clinically and statistically indistinguishable performance. These results support the conclusion that Argos Infinity is substantially equivalent to the predicate Argos Monitor.

7. Conclusions

Argos Infinity has been shown to be as safe and effective as the predicate.