December 13, 2018

Retia Medical, LLC
Jerry Korten
VP R&D
7 Dana Rd. Suite 111
Valhalla, New York 10595

Re: K181372
Trade/Device Name: Argos
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: November 8, 2018
Received: November 9, 2018

Dear Jerry Korten:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.12.13 15:41:34 -05'00'

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181372

Device Name
Retia Medical, LLC : Argos Monitor

Indications for Use *(Describe)*

The Argos Cardiac Output monitoring device is intended for use on patients above the age of 18. It is intended to be used as a hemodynamic monitor for monitoring cardiac output and its derived parameters on patients in the intensive care unit or the operating room.

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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5. 510(K) SUMMARY

5.1. Submitter

Retia Medical
7 Dana Rd
Valhalla, NY 10595
914 594 1986

Contact(s): Jerry Korten

Date Prepared: May 15, 2018

5.2. Device

Name of Device:	Argos Monitor
Common or Usual Name	Argos
Classification Name:	Cardiovascular (21 CFR 870.1435)
Regulatory Class:	Class II
Product Code:	DXG

5.3. Predicate Device

Predicate Name and 510(k) Number:

Primary Predicate: Edwards Lifesciences: Flotrac Vigileo Arterial Pressure Cardiac Output (APCO) Monitor (K043065).
Secondary Predicate: LiDCOplus monitor (K023960).

5.4. Device Description

The Argos Monitor is a portable hemodynamic monitor that calculates Cardiac Output and other derived parameters, including cardiac index (CI), stroke volume (SV), stroke volume index (SVI), systemic vascular resistance (SVR), systemic vascular resistance index (SVRI), mean arterial pressure (MAP), heart rate (HR), and pulse pressure variation (PPV) based on a proprietary algorithm that analyzes the blood pressure waveform and user-entered patient demographic information (age, height weight and gender). The blood pressure waveform is input into the monitor via a connection with either a radial arterial catheter or the analog blood pressure signal output of a vital signs monitor. The scientific method that underlies the algorithm is based on a novel signal processing technique to determine the parameters of the well-established Windkessel model of the circulation in order to calculate cardiac output.

The Argos Monitor comes with a touchscreen monitor and computer system enclosed in a rigid plastic housing and a power cable. Cables to connect the monitor to a radial blood pressure transducer or to the analog blood pressure signal output of a vital signs monitor are also

provided according to the setup and needs of the individual institution. The Monitor may be attached to a pole or a table stand via a standard screw interface pattern.

5.5. Indications for Use

The Argos Cardiac Output monitoring device is intended for use on patients above the age of 18. It is intended to be used as a hemodynamic monitor for cardiac output monitoring and its derived parameters on patients in the intensive care unit or the operating room.

5.6. Intended Use

The Argos Cardiac Output monitor is used for the continuous measurement cardiac output from an intravascular radial arterial blood pressure signal. This signal is derived from a blood pressure transducer or from the analog output of a vital signs monitor. The device is intended to be used by clinicians on critically ill patients in an operating room or in an intensive care unit.

5.7. Comparison of Technological Characteristics with the Predicate Device

The design, materials, basic product function, configuration and parameters displayed for the Retia Argos monitor and the predicate devices share several similar characteristics as follows:

1. All three systems house a computer-driven display system in a plastic enclosure with an external power supply source.
2. All three systems can be pole mounted.
3. All three systems can take input from a blood pressure transducer.
4. All three systems use a pre-programmed computer that uses pulse contour analysis to analyse a blood pressure signal along with user-entered patient demographic data (age, height, weight and gender) to calculate cardiac output and other derived hemodynamic parameters (CI, SV, SVI, SVR, SVRI).
5. The Retia Argos and the reference predicate device from LiDCO both calculate pulse pressure variation (PPV) from the input blood pressure waveform.
6. The Retia Argos and the reference predicate device from LiDCO can both input the analogue blood pressure signal output from an external vital signs monitor.

The main differences between the Retia Argos monitor and the predicate device are as follows:

1. All three systems systems use proprietary versions of the pulse contour analysis algorithms to analyse the blood pressure signal. Accordingly, the accuracy of the algorithm used in the Argos monitor was verified via clinical testing using the pulmonary artery catheter as a reference for the CO measurement and shown to have as low or lower errors than the predicate Edwards device.
2. The Retia Argos does not provide an oximetry catheter nor compute parameters associated with this measurement method.

3. The Retia Argos has a battery backup that automatically switches in if the monitor is disconnected from the AC power input, allowing use during transport. The predicate devices do not have a battery.

Verification and validation testing was conducted to compare the mechanical, electrical, software, usability, and clinical accuracy of the Retia Argos monitor to the predicate devices, considering the technological similarities and differences as described. The Argos monitor passed all verification and validation testing and was shown to be safe, effective and substantially equivalent to the predicate device.

5.8. Performance Data

The Argos CO Monitor has successfully passed functional and performance testing, including electrical and mechanical testing, environmental testing, shipping tests, software verification and validation, clinical usability testing, and comparison testing with the predicate device on clinical data.

The monitor was assessed and/or tested for and met the following standard requirements:

1. IEC 60601-1
2. IEC 60601-1-2
3. IEC 60601-2-34
4. IEC 60601-1-8
5. ISTA 2A
6. ISO 10993-1

Clinical usability testing for the monitor was performed on 15 clinical users, comprising physicians and nurses who work in the ICU and OR. All users were successfully able to set up the monitor, connect the appropriate cables, enter the patient demographic information, configure the displayed parameters, and interpret the information provided, including alarms.

The clinical performance of the Argos monitor was assessed in comparison to the predicate device on 40 patients, 20 each from the OR and ICU. The blood pressure waveforms from all patients were connected to both the Argos monitor and the predicate device. No adverse effects or complications were noted during the study. The accuracies of the Argos monitor and the predicate device were assessed using the pulmonary artery catheter as the reference for all measurements. The data demonstrated that the Argos monitor has the same or lower errors in measurement compared to the reference than the errors shown by the predicate device compared to the reference.

In conclusion, the results from the nonclinical and clinical tests demonstrate that the Argos monitor is as safe, as effective and performs as well as or better than the predicate device for its intended use.

5.9. Conclusions

The Retia Argos monitor has been shown to be safe and effective as the predicate.