December 1, 2022

Abbott
Kim Bondarenko
Manager, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, California 94588

Re: K222297
Trade/Device Name: CentriMag Pre-connected Pack
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ, KFM, DTQ, DTR, DWA, DWF, KRI
Dated: November 17, 2022
Received: November 18, 2022

Dear Kim Bondarenko:

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/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 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 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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222297

Device Name
CentriMag™ Pre-connected Pack

Indications for Use *(Describe)*
The CentriMag™ Pre-connected Pack is indicated for use with the CentriMag™ Acute Circulatory Support System to provide physiologic gas exchange of the blood and to pump a patient's blood through an extracorporeal circuit for periods lasting less than six (6) hours for the purpose of providing either:
(i) Full or partial cardiopulmonary bypass during open surgical procedures on the heart or great vessels; or
(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807 (particularly §807.92).

I. SUBMITTER

Date Prepared:	July 29, 2022
Submitter's Name & Address:	Abbott 6035 Stoneridge Drive Pleasanton, CA 94588
Establishment Registration No.	2916596
Contact Person:	Kim Bondarenko Phone: (925) 460-7361

II. DEVICE

Trade or Proprietary Name:	CentriMag™ Pre-connected Pack
Common or Usual Name:	Pre-connected blood pump and oxygenator components for cardiopulmonary bypass
Classification Name:	Cardiopulmonary bypass oxygenator
Classification Regulation:	21 CFR 870.4350 Cardiopulmonary bypass oxygenator
Product Code:	DTZ, KFM, DWA, DTQ, DTR, DWF, and KRI
Regulatory Class:	Class II

III. LEGALLY MARKETED PREDICATE DEVICE

Predicate Device:

- OXY-1 System (K200109)

Reference Devices:

- Rotaflow Centrifugal Pump with Softline Coating (K090515)
- Quadrox-iD Adult Oxygenator (K150267)
- HLM Tubing Set with Softline Coating (K090533)
- CentriMag Acute Circulatory Support System (K200306)
- Eurosets PMP Sterile Oxygenator (K141492)

IV. DEVICE DESCRIPTION

CentriMag Pre-connected Pack is to be used with the CentriMag™ Acute Circulatory Support System components (console, motor, flow probe and monitor) to provide extracorporeal circulation for full or partial cardiopulmonary bypass support for less than 6 hours. The CentriMag™ Pre-connected Pack contains sterile disposable components: a blood pump, oxygenator, and priming bag pre-connected by tubing. The pack also includes disposable accessories commonly used in the setup of pump and oxygenator connections to the cardiopulmonary bypass extracorporeal circuit.

V. INDICATIONS FOR USE

The CentriMag™ Pre-connected Pack is indicated for use with the CentriMag™ Acute Circulatory Support System to provide physiologic gas exchange of the blood and to pump a patient's blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence of the CentriMag Pre-connected Pack to be used with the CentriMag Acute Circulatory Support System was demonstrated through technological characteristics similarities with the identified predicate device; performance testing, and comparative testing using reference devices. CentriMag Pre-connected Pack and Abiomed's OXY-1 System (K200109) have the same intended use, clinical setting, target user, tubing connections and principle of operation. The minor technological differences do

not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicates.

VII. PERFORMANCE DATA

Performance tests were conducted on the CentriMag Pre-connected Pack to support the determination of substantial equivalence and demonstrate the integrity, durability, and reliability of the devices over the intended shelf life.

Performance Testing

- The following testing was conducted as recommended in "*Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions Final Guidance for Industry and FDA Staff*" dated November 13, 2000:
    - Gas Exchange (oxygen and carbon dioxide transfer)
    - Blood Pathway Pressure drop
    - In vitro Hemolysis
    - Blood, Gas, and Water Pathway Integrity
    - Heat Exchange Efficiency and Water Pathway Pressure Drop
- Usable Life (Reliability) Testing
- Functionality and Integrity Testing of Accessories
- Shelf Life Testing
- Validation of EtO Sterilization
- Packaging Testing

No animal studies or clinical studies are required.

Biocompatibility Testing

Biocompatibility testing of the CentriMag Pre-connected Pack was conducted in accordance with FDA biocompatibility guidance *Use of International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* per ISO 10993-1. The results meet the requirements for external communicating medical device with limited (≤ 24 hour) circulating blood contact.

- Genotoxicity
- Hemocompatibility
- Cytotoxicity

- Implantation
- Sensitization, Irritation
- Systemic Toxicity
- Particulate Matter
- Volatile Organic Compounds

VIII. CONCLUSION

CentriMag Pre-connected Pack to be used with CentriMag Acute Circulatory Support System has the same intended use as the identified predicate device OXY-1 System. The comparison of technological characteristics between subject and predicate device, and performance testing conducted on the subject device including comparator testing with identified reference devices do not raise different questions of safety and effectiveness. The subject device and the predicate device are substantially equivalent.