January 26, 2024

Abbott Medical
Manas Lele
Senior Manager
6035 Stoneridge Drive Pleasanton
Pleasanton, California 94588

Re: K234118
Trade/Device Name: CentriMag™ Acute Circulatory Support System
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QNR, DWA
Dated: December 27, 2023
Received: December 28, 2023

Dear Manas Lele:

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.

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,

Eric E. Richardson -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234118

Device Name

CentriMag™ Acute Circulatory Support System

Indications for Use *(Describe)*

The CentriMag Extracorporeal Blood Pumping System is a non-roller-type cardiopulmonary and circulatory bypass blood pump used 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 (i.e., circuit includes an oxygenator) 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

The CentriMag™ Blood Pump for use with the CentriMag™ Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

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) 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, and in particular §807.92.

1. SUBMITTER'S NAME	Abbott Medical
2. SUBMITTER'S ADDRESS	6035 Stoneridge Drive, Pleasanton CA 94588
3. CONTACT PERSON	Manas Lele, Senior Manager Regulatory Affairs (925) 460-7086
4. ALTERNATE CONTACT PERSON	Lucy Tan, Senior Director Regulatory Affairs (925) 416-9778
5. DATE PREPARED	January 26, 2024
6. DEVICE TRADE NAME	CentriMag™ Acute Circulatory Support System CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System
7. DEVICE COMMON NAME	CentriMag Extracorporeal Blood Pumping System
8. DEVICE CLASSIFICATION NAME	Class II, DWA, 21 CFR 870.4380 Control, Pump Speed, Cardiopulmonary Bypass Class II, QNR, 21 CFR 870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
9. ASSOCIATED PRODUCT CODES:	DWA, QNR

10. PREDICATE DEVICE NAME

CentriMag™ Acute Circulatory Support System (K200306)

CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System (K222038)

Note: The CentriMag Drainage (Venous) and Return (Arterial) Cannula Kits (K200306) are not part of this Special 510(k) premarket notification.

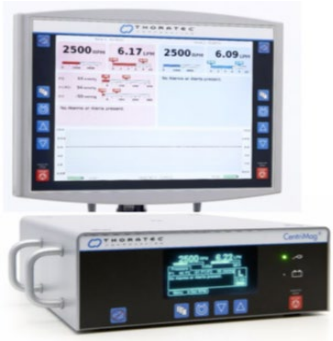
11. DEVICE DESCRIPTION

The CentriMag™ Acute Circulatory Support System, hereafter referred to as the CentriMag System, was designed to provide temporary mechanical circulatory support. To date, the CentriMag system in the United States (US) is indicated as a component of an extracorporeal bypass circulatory support circuit for use during cardiopulmonary bypass (CPB) surgery (up to 6 hours), it is also indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. The CentriMag System provides circulatory assistance for patients in acute hemodynamic compromise, a population whose treatment options are limited.

The CentriMag System is composed of:

- CentriMag Primary Console
- CentriMag Motor
- CentriMag Blood Pump
- CentriMag Flow Probe
- Mag Monitor

CentriMag Blood Pump



CentriMag Console and Mag Monitor

CentriMag Motor

Flow Probe(fits standard 3/8" tubing)

The CentriMag Motor is a reusable, non-sterile component of the CentriMag System. The CentriMag Motor holds the blood pump and drives the impeller inside the blood pump. The motor turns the magnet (and impeller) within the blood pump (Full MagLev™ technology) at a speed that is set on the console by the user. When the impeller is rotated, a pressure gradient develops between the center and outside edge of the pump, causing blood to flow from the inflow to the outflow port of the pump. The amount of flow through the pump depends on the speed of the impeller, and the difference between the inlet and outlet pressures.

12. INDICATIONS FOR USE

This Special 510k does not include changes to the cleared indications for use. The FDA 510k cleared indications are as follows:

1. The CentriMag Extracorporeal Blood Pumping System is a non-roller-type cardiopulmonary and circulatory bypass blood pump used 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 (i.e., circuit includes an oxygenator) 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

2. The CentriMag™ Blood Pump for use with the CentriMag™ Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

13. SUBSTANTIAL EQUIVALENCE

The subject device CentriMag Acute Circulatory Support System (CentriMag Motor with snap in motor locking feature) has an intended use, technological characteristics, and performance characteristics which are substantially equivalent to the predicate CentriMag Acute Circulatory Support System (CentriMag Motor with screw locking feature).
No other components of the CentriMag System are affected by the design change proposed in this Special 510(k) premarket notification.

14. PERFORMANCE DATA

The CentriMag Motor for use with CentriMag System performance characteristics were demonstrated through the following verification testing and usability validation testing to support the determination of substantial equivalence.

Following Verification Testing was performed to support the Motor Locking Feature with snap in levers:

- Mechanical Testing was executed that included Environmental testing for drop, shock and vibration.
- Durability Testing
- Cleaning testing for the CentriMag Motor.
- Operating Manual Verification Testing

Following Validation Testing was performed to support the Motor Locking Feature with snap in levers:

- Summative Human Factors Validation Testing was executed for the changes in user interface.

The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate device.

15. CLINICAL PERFORMANCE

Clinical testing was not performed on the redesigned motor locking feature, as this design change did not impact the clinical performance of the device.

16. CONCLUSION

Given that the intended use and the technological characteristics of the subject device CentriMag Acute Circulatory Support System (CentriMag Motor with snap in locking feature) are the same to the predicate device CentriMag Acute Circulatory Support System (CentriMag Motor with screw locking feature) and the results of the performance testing demonstrate no differences in safety and effectiveness of the subject device when compared to the predicate device, CentriMag Motor with Snap in Motor Locking Feature is substantially equivalent to the Abbott's predicate device .