December 8, 2022

Abbott (formerly Thoratec Corporation)
Meera Mehta
Project Manager, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, California 94588

Re: K222038
Trade/Device Name: CentriMag™ Blood Pump for use with 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
Dated: November 21, 2022
Received: November 21, 2022

Dear Meera Mehta:

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)*
K222038

Device Name

CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System

Indications for Use *(Describe)*

The CentriMag™ Blood Pump for use with 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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6. 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.

I. SUMBITTER

Date Prepared:	July 8, 2022
Submitter's Name & Address:	Abbott 6035 Stoneridge Drive Pleasanton, CA 94588
Establishment Registration No.	2916596
Contact Person:	Meera Mehta 6035 Stoneridge Dr, Pleasanton, CA-94588 Project Manager, Regulatory Affairs Ph: 925-315-6483

II. DEVICE

Trade or Proprietary Name:	CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System
Common or Usual Name:	CentriMag System
Classification Name:	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulation Number:	21 CFR 870.4100
Regulatory Class:	Class II (special controls)
Product Code:	QNR

III. PREDICATE DEVICE

Predicate device: FDA final order for Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure (21 CFR 870.4100, section (b) Class II (special controls)).

Secondary/Reference device: Medtronic BPX-80 Centrifugal Pump (K973011)

IV. DEVICE DESCRIPTION

The CentriMag™ Blood pump for use with CentriMag™ Acute Circulatory Support System (hereafter referred to as the CentriMag System) is designed to provide assisted extracorporeal circulation and physiologic gas exchange of patients' blood for adult patients with acute respiratory and/or acute cardiopulmonary failure.

The CentriMag System was designed to provide temporary mechanical circulatory support. The CentriMag System provides circulatory assistance for patients in acute hemodynamic compromise, a population whose treatment options are limited.

- CentriMag 2nd Generation Primary Console
- CentriMag Motor
- CentriMag Blood Pump
- Flow Probe
- Mag Monitor (optional)

The CentriMag System features a centrifugal flow pump with inflow and outflow ports that are at right angles to one another, and a magnetically levitated impeller (Full MagLev™ technology).

The CentriMag Motor is a reusable, non-sterile component of the CentriMag Acute Circulatory Support System. The CentriMag Motor holds the blood pump and drives the impeller inside the blood pump. When the pump is inserted into the motor and activated, the internal impeller is electromagnetically levitated and centered, eliminating the need for shafts, seals, and bearings in the pump. Utilizing magnetic levitation technology (Full MagLev™ technology) to suspend and spin the impeller eliminates bearing and seal friction, resulting in minimal heat generation and wear of the pump components. the console is used to control pump speed, the resultant blood flow, and monitor the operation of the system. A cable connects the console to the motor, allowing flexibility in the pump motor and pump positioning.

Note: The CentriMag Drainage (Venous) and Return (Arterial) Cannula Kits (K200306) are not part of this 510(k) premarket notification seeking clearance per *21 CFR 870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure*, section (b) Class II (special controls).

V. INDICATION FOR USE

The CentriMag™ Blood Pump for use with 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence of the CentriMag Blood Pump for use with CentriMag Acute Circulatory Support System was demonstrated by meeting the special controls in FDA Final Order, *21 CFR 870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure*, *section (b) Class II (special controls)* and through bench testing, mechanical testing, electrical safety and electromagnetic compatibility testing, usability, and software testing.

- ***Technological Characteristics:*** Geometry and design parameters of the subject device are consistent with devices intended for use in extracorporeal life support procedures. The subject device is designed to be compatible with other extracorporeal circuit devices and accessories.
- ***Biocompatibility:*** The subject device (CentriMag blood pump) is demonstrated to be biocompatible 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.
- ***Sterility and Shelf-life:*** The CentriMag blood pump has been validated over the stated shelf life of the device to ensure a minimum sterility assurance level (SAL) of 10^{-6} as described in ANSI/AAMI/ISO 11135, Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices.
- ***Non-clinical Performance:*** Substantial equivalence has been demonstrated by performance testing (bench), mechanical integrity, durability, and reliability.
- ***In vivo Evaluation:*** *In vivo* evaluation demonstrates the subject device's performance over an intended duration of use.
- ***Labeling***: The labeling summarizes non-clinical and clinical performance of the CentriMag System and provides adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure.

VII. PERFORMANCE DATA

The CentriMag Blood Pump for use with CentriMag Acute Circulatory Support System performance characteristics were demonstrated through bench testing, mechanical testing, electrical safety and electromagnetic compatibility testing, usability, and software testing to support the determination of substantial equivalence.

Component	Test
System (console, monitor, pump, motor)	30-day reliability
	In Vivo Animal Testing
	Water Ingress Resistance
	Electrical Safety & EMC
Motor	Thermal Operating conditions
	Fluid Intrusion
Console & Monitor	Battery life
	Battery run time

	Rough Handling (Shock/Drop/Vibration)
	Environmental Test
	Software validation
Blood Pump	HQ performance
	In Vitro Hemolysis, Platelet count, WBC, RBC, hematocrit and thrombus
	Air handling
	Priming volume
	Leak and burst pressure testing
	Sterilization
	Transportation distribution / simulation
	Shelf life
	Biocompatibility

VIII. CLINICAL SUMMARY

This submission included a pre-specified statistical analysis plan from the ELSO Registry. The propensity matched analysis demonstrates the safety and effectiveness of the CentriMag Blood Pump for use with CentriMag Acute Circulatory Support System as part of an ECMO circuit to provide long-term assisted extracorporeal circulation and physiologic gas exchange of the blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure. This pre-specified analysis focused on seven ECMO-related clinical complications and outcomes.

The results of the propensity analysis did not identify any statistically significant or clinically meaningful differences in the seven ECMO-related clinical outcomes between the CentriMag System and the comparator group. This analysis demonstrated the CentriMag Blood pump for use with CentriMag System as part of an ECMO circuit is substantially equivalent to other devices used in the same manner.

IX. CONCLUSION

The CentriMag Blood Pump along with CentriMag Acute Circulatory Support System met the special controls in 21 CFR 870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure, section (b) Class II (special controls) and are substantially equivalent to the predicate device. The information and data in this 510(k) premarket notification demonstrate that the CentriMag Blood Pump for use with CentriMag Acute Circulatory Support System are substantially equivalent to the predicate 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.