July 10, 2019

Thoratec Corporation (now part of Abbott)
Lori Dondiego
Associate Director, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, California 94588

Re: K191557
Trade/Device Name: CentriMag Acute Circulatory Support System
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA
Dated: June 10, 2019
Received: June 12, 2019

Dear Lori Dondiego:

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,

For
Fernando Aguel
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

3.0 Indications for Use Statement (Form FDA 3881)

Applicant: **Thoratec (now part of Abbott)**

510(k) Number (if known): K191557

Device Name: **CentriMag™ Acute Circulatory Support System**

Indications for Use:

The CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use X **AND/OR** **Over-The-Counter Use _____**

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4.0 510(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.

A. Application Information

Date Prepared:	June 10, 2019
Submitter's Name & Address:	Thoratec (now part of Abbott) 6035 Stoneridge Drive Pleasanton, CA 94588 Establishment Registration No.: 2916596
Owner / Operator No.:	1415939
Contact Person:	Kim Bondarenko Manager, Regulatory Affairs Ph: 925-734-4097 Fax: (925) 847-8628 Thoratec (now part of Abbott) 6035 Stoneridge Drive Pleasanton, CA 94588

B. Device Information

Trade or Proprietary Name:	CentriMag™ Acute Circulatory Support System
Common or Usual Name:	CentriMag Extracorporeal Blood Pumping System
Classification Name:	Class II, DWA, 21 CFR – 870.4380 Control, Pump Speed, Cardiopulmonary Bypass
Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Legally Marketed Predicate Device

CentriMag Extracorporeal Blood Pumping System (K020271) – Original blood pumping system with 1st generation Primary console and Back-up console.

CentriMag 2nd Generation Primary Console and Mag Monitor (K102129) – Redesigned (2nd generation) console and new peripheral monitor introduced.

D. Device Description

The CentriMag™ 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). 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 (optional, not shown)

CentriMag Blood Pump

CentriMag Console

CentriMag Motor

Flow Probe
(fits standard 3/8” tubing)

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. 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.

E. Intended Use

The CentriMag Motor is intended for use only with the CentriMag Acute Circulatory Support System. The CentriMag System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The technological characteristics of the CentriMag Acute Circulatory Support System have not changed. The redesigned CentriMag Motor cable with enhanced (longer) bend protection is the focus of this special 510(k) notification. The fundamental technological and functional characteristics of the motor and its cable are the same as the predicate device motor cable.

G. Comparison to Predicate Device

The redesigned CentriMag Motor cable assembly with longer bend protection has an indication for use, technological characteristics, and performance characteristics which are substantially equivalent to the predicate CentriMag Motor cable. Due to this, the redesigned CentriMag Motor cable structure with enhanced bend protection raises no new safety or effectiveness concerns. These design modifications enhance cable flexibility and durability, and reduce the impact of rough handling and the occurrence of cable breaks and short circuiting.

No other components of the CentriMag Acute Circulatory Support System are affected by the design changes proposed in this Special 510(k) premarket notification.

H. Summary of Performance Data

Comparison bench testing was performed to evaluate the mechanical performance characteristics of the redesigned CentriMag Motor cable with new bend protection with those of the current motor cable design.

The following mechanical performance verification tests were conducted on both designs:

Motor Cable Endurance Test:

Evaluated the durability and functionality of the Motor cable and new bend protection assembly under simulated severe handling to demonstrate the new design meets the expected service life of the CentriMag Motor under worst-case conditions. In addition, visual inspection of the test bend area showed the integrity of the outer surface of the motor cable or bend protection in the area of bending.

Motor Cable Kink Test:

Verified the Motor cable with new bend protection can tolerate excessive kinking or bending with small radius (e.g. when the cable is wound around the housing for storage) for the targeted expected service life. Visual inspection showed no defects on the surface of the motor cable or bend protection in the area of bending.

The redesigned CentriMag Motor cable with new custom-made bend protection successfully passed the cable endurance (bend) and kink test protocols, both designed to represent extreme / severe handling scenarios. The redesigned robust motor cable with extended bend relief successfully passed both tests (no failures), whereas the original cable design was less robust under high stress. Therefore, the redesigned CentriMag Motor cable with new bend protection performance test results demonstrate it to be substantially equivalence to the performance of the predicate CentriMag Motor cable design. Therefore, it can be concluded that the redesigned Motor cable offers enhanced cable flexibility and durability and improved protection from bending and kinking at the bend protection over the current commercial cable design.

Compliance to IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance for the redesigned CentriMag Motor cable and new bend protection assembly has been confirmed, and it is therefore, substantially equivalent.

Given the nature of the proposed change, pre-clinical in-vivo testing, biocompatibility, software or sterility testing was not necessary.

No other device components of the CentriMag Motor assembly, or of the CentriMag Circulatory Support System, are affected by the design changes proposed in this Special 510(k) premarket notification.

I. Clinical Performance

Clinical testing was not performed on the redesigned motor cable.

J. Conclusion

The redesigned CentriMag Motor cable is substantially equivalent to the predicate CentriMag System motor cable.