March 6, 2020

Abbott (formerly Thoratec Corporation)
Bindya Gadhia
Senior Specialist, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, California 94588

Re: K200306
Trade/Device Name: CentriMag Acute Circulatory Support System, CentriMag Return (Arterial) Cannula Kit, CentriMag Drainage (Venous) Cannula Kit
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA, DWF
Dated: February 5, 2020
Received: February 6, 2020

Dear Bindya Gadhia:

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

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)*
K200306

Device Name
CentriMag™ Acute Circulatory Support System

Indications for Use *(Describe)*

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.)

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.

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)*
K200306

Device Name
CentriMag™ Return (Arterial) Cannula Kit

Indications for Use *(Describe)*

The CentriMag Return (Arterial) Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

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

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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)*
K200306

Device Name
CentriMag™ Drainage (Venous) Cannula Kit

Indications for Use *(Describe)*

The CentriMag Drainage (Venous) Cannula is indicated for use with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

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)

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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.

A. Application Information

Date Prepared:	February 5, 2020
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:	Bindya Gadhia Senior Specialist, Regulatory Affairs Ph: 925-227-5834 Thoratec (now part of Abbott) 6035 Stoneridge Drive Pleasanton, CA 94588

B. Device Information

Trade or Proprietary Name:	CentriMag™ Acute Circulatory Support System CentriMag Return (Arterial) Cannula Kit CentriMag Drainage (Venous) Cannula Kit
Common or Usual Name:	CentriMag Extracorporeal Blood Pumping System Cardiopulmonary bypass cannula
Classification Name:	Class II, DWA, 21 CFR 870.4380 Control, Pump Speed, Cardiopulmonary Bypass Class II, DWF, 21 CFR 870.4210 Cardiovascular bypass vascular catheter, cannula, or tubing
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

Subject Device - this 510(k)	Legally Marketed Predicate Device
CentriMag™ Acute Circulatory Support System	CentriMag™ Acute Circulatory Support System (K191557)
CentriMag Return (Arterial) Cannula Kit	CentriMag Return (Arterial) Cannula Kit (K152161)
CentriMag Drainage (Venous) Cannula Kit	CentriMag Drainage (Venous) Cannula Kit (K152190)

D. Device Description

i. CentriMag™ Circulatory Support System

The CentriMag™ Circulatory Support System, hereafter referred to as the CentriMag System, was designed to provide temporary mechanical circulatory support. 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)

ii. CentriMag Return (Arterial) Cannula Kit

The Thoratec CentriMag Return (Arterial) Cannula Kit consists of the return (arterial) cannula and several accessories used in the surgical placement procedure. The cannula and all kit accessories are sterile, single-use, disposable devices. The cannula kit is designed for use with the Thoratec CentriMag® Extracorporeal Blood Pumping System.

iii. CentriMag® Drainage (Venous) Cannula Kit

The Thoratec CentriMag® Drainage (Venous) Cannula Kit consists of the drainage (venous) cannula and several accessories used in the surgical placement procedure. The cannula and all kit its accessories are sterile, single use, disposable devices. The cannula kit is designed for use with the Thoratec CentriMag® Extracorporeal Blood Pumping System.

E. Intended Use

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.)

The CentriMag Cannulae (arterial and drainage cannula) are designed to serve as conduits to transport blood between the heart and the extracorporeal blood pump. The Cannulae are intended for use for circulatory support during cardiac surgery for cardiopulmonary surgical procedures for up to six hours.

F. Technological Characteristics

The technological characteristics of the CentriMag Acute Circulatory Support System, CentriMag Return (Arterial) Cannula Kit and CentriMag Drainage (Venous) Cannula Kit have not changed from the predicate devices.

G. Comparison to Predicate Device

Components of the CentriMag Acute Circulatory Support System, CentriMag Return (Arterial) Cannula Kit and CentriMag Drainage (Venous) Cannula Kit are not affected by the labeling changes proposed in this Special 510(k) premarket notification. The labeling changes make the contraindications consistent among all labeling, add and/or strengthen warnings and precautions, and generally align and update the content for consistency.

H. Summary of Performance Data

The performance characteristics of the CentriMag Acute Circulatory Support System, CentriMag Return (Arterial) Cannula Kit and CentriMag Drainage (Venous) Cannula Kit have not changed. The labeling changes included in this 510(k) are for the Thoratec (now Abbott's) devices (predicates listed above) and do not require performance data to evaluate the change.

I. Clinical Performance

Clinical testing was not necessary for the labeling changes stated herein since the changes do not impact the design and performance of the devices.

J. Conclusion

CentriMag Acute Circulatory Support System, CentriMag Return (Arterial) Cannula Kit and CentriMag Drainage (Venous) Cannula Kit are substantially equivalent to their predicates in K191557, K152161 and K152190, respectively.