



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Thoratec Corporation
Lori DonDiego
Senior Manager, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, VA 94588

Re: K152161

Trade/Device Name: Thoratec CentriMag Return (Arterial) Cannula Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: August 31, 2015
Received: September 2, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

Applicant: **Thoratec Corporation**

510(k) Number (if known): K152161

Device Name: **Thoratec CentriMag® Return (Arterial) Cannula Kit**

Indications for Use:

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

5.0 510(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: July 31, 2015

Submitter's Name & Address: Thoratec Corporation
 6035 Stoneridge Drive
 Pleasanton, CA 94588
 Establishment Registration No.: 2916596
 Owner / Operator No.: 9045196

Contact Person: Lori DonDiego
 Sr. Manager, Regulatory Affairs

Ph: 925-734-6921
 Fax: (925) 847-8628

Thoratec Corporation
 6035 Stoneridge Drive
 Pleasanton, CA 94588

B. Device Information

Trade or Proprietary Name: CentriMag Return (Arterial) Cannula Kit

Common or Usual Name: Cardiopulmonary bypass cannula

Classification Name: Cardiovascular bypass vascular catheter, cannula, or tubing (DWF, 21 CFR – 870.4210), Class II

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

Thoratec CentriMag Return Cannula Kit (K110980)

D. Device Description

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 (K020271).

The Cannula Kit includes the following accessories:

QTY	Kit Component
1	Return (Arterial) Cannula Body
1	Connector, 3/8-inch, barbed
1	Introducer
1	Hemostasis Seal
1	Cap (with Umbilical tape)
1	Porous Plug
1	Guidewire Assembly
1	Introducer Needle
4	Suture Rings (small)
4	Suture Rings (medium)
4	Tip Rings

E. Intended Use

The CentriMag Cannulae 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 modified CentriMag Return (Arterial) Cannula Kit are the same as the predicate device.

G. Comparison to Predicate Device

The modified CentriMag Return (Arterial) Cannula Kit has the same indication for use, technological characteristics, and performance attributes which essentially renders the modified device equivalent to the predicate device. Moreover, the new device raises no new questions concerning safety or effectiveness. The modification improves upon the reliability of the connection between the connector and the cannula body.

H. Summary of Performance Data

The modified CentriMag Return (Arterial) Cannula Kit has successfully undergone performance testing to demonstrate substantial equivalence to the predicate device.

The following performance and dimensional verification tests have been conducted on the redesigned cannula with successful results:

- Flex Test
- Tensile Strength Test
- Chemical Resistance Test
- Pressure Test
- Suture and Tip Ring Security and Deformation Test
- Dimensional Verification Examination
- Cannula Body Material Examination

All testing employed devices that were exposed to 2x sterilized, accelerated-aging to simulate a real-time equivalent of 1-year, and heated saline soak for 30-days.

Additional verification involved materials evaluation for chemical characterization and biocompatibility to address raw material supplier changes. Lastly, a reduced confirmatory microbiological performance qualification (sterilization revalidation) was conducted.

The risk management methods used to assess the design modifications to the CentriMag Return (Arterial) Cannula were a Risk Analysis and a Failure Modes and Effects Analysis (FMEA).

I. Clinical Performance

Clinical testing was not performed.

J. Conclusion

The redesigned CentriMag Return (Arterial) Cannula Kit is substantially equivalent to the current CentriMag Return Cannula Kit (K110980).