



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 27, 2015

Medtronic, Inc.
Chelsea Pioske
Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K151110

Trade/Device Name: Intercept Filtered Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN, DTP
Dated: April 24, 2015
Received: April 27, 2015

Dear Chelsea Pioske:

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" (21 CFR 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,



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

Enclosure

Indications for Use

510(k) Number (if known)
K151110

Device Name
Intersept™ Filtered Cardiomy Reservoir

Indications for Use (Describe)

The Intersept filtered cardiomy reservoir is indicated for use in the cardiopulmonary bypass circuit during surgery for:

- an air/fluid separation chamber;
- a temporary storage reservoir for priming solution and blood;
- the filtration of particulates from bank blood and the storage and filtration of blood recovered from the field by suction;
- the addition of medications or other fluids.

The Intersept filtered cardiomy reservoir is also indicated for use after open heart surgery for:

- the post-operative collection of autologous blood from the chest and the aseptic return of blood to the patient for volume replacement.

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

Date Prepared: April 23, 2015

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Chelsea Pioske
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Trade Name: Intercept™ Filtered Cardiotomy Reservoir
Classification Name: Reservoir, Blood, Cardiopulmonary Bypass; Defoamer, Cardiopulmonary Bypass
Regulation Number: 21 CFR 870.4400, 21 CFR 870.4230
Product Classification: Class II
Product Code: DTN, DTP

Name of Predicate Device: Intercept® Cardiotomy Reservoir with Filter

Device Description

The Intercept™ Filtered Cardiotomy Reservoir is a single-use, device with a sterile, nonpyrogenic fluid path. The maximum capacity of each reservoir is 2,600 ml. The maximum recommended flow rate is 2 liters per minute (LPM).

Each reservoir has eight luer or 1/4" (0.6 cm) ID access ports;

- four suction access ports
- two pre-defoamer and two post-defoamer access ports. One of the post-defoamer access ports is intended for use as a vent.

Each Intersept™ Filtered Cardiotomy Reservoir contains an open cell polyurethane defoamer with a 20 micron microaggregate filter covered with a polyester sleeve.

Indications for Use

The Intersept filtered cardiotomy reservoir is indicated for use in the cardiopulmonary bypass circuit during surgery for:

- an air/fluid separation chamber;
- a temporary storage reservoir for priming solution and blood;
- the filtration of particulates from bank blood and the storage and filtration of blood recovered from the field by suction;
- the addition of medications or other fluids.

The Intersept filtered cardiotomy reservoir is also indicated for use after open heart surgery for:

- the post-operative collection of autologous blood from the chest and the aseptic return of blood to the patient for volume replacement.

Contraindications

This product used for any other purposes than for the indicated use is the responsibility of the user.

The cardiotomy reservoir is contraindicated for use in post-operative chest drainage/autotransfusion procedures when:

- there is an air leak in the lung or gross perforations to the chest wall exist;
- pericardial, mediastinal, pulmonary or systemic infection or malignancy is present;
- gross contamination (e.g., bone cement, lymphatic failure, perforated intestine) is present or suspected;
- aspirating blood from a site containing topical hemostatic agents, bactericidal wound irritants or antibiotics not intended for parenteral administration;
- the chest is open and vacuum is applied;
- protamine has been administered prior to the reservoir being removed from the bypass circuit;
- the patient is returned to surgery for any reason;
- vented chest tubes not incorporating vent flow regulation such as stopcock are used.

Comparison to Predicate Devices

A comparison of the Intersept™ Filtered Cardiotomy Reservoir to the predicate device (the Intersept® Cardiotomy Reservoir with Filter) indicates the following similarities:

- Intended Use: The intended use is the same as predicate device.
- Design: The overall design is the same as the predicate.
- Materials: The material types used are the same as the predicate.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance is substantially equivalent to the predicate and/or reference device.

Summary of Testing

Testing has demonstrated that the Intersept™ Filtered Cardiomy Reservoir is substantially equivalent to the predicate.

The following tests were conducted:

Component	Base Material Changes	Verification/Validation	Results
Frame	Current: Polypropylene	Filtration Efficiency	Pass
		Blood Trauma	Pass
	Proposed: Polypropylene	Biocompatibility	Pass

Conclusion

The data included in this submission is sufficient to demonstrate substantial equivalence of the Intersept™ Filtered Cardiomy in terms of safety and effectiveness as compared to the predicate device, the Intersept® Cardiomy Reservoir with Filter.