



Food and Drug Administration  
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July 15, 2015

Medtronic, Inc.  
Jacqueline A. Hauge  
Principal Regulatory Affairs Specialist  
8200 Coral Sea Street NE  
Mounds View, MN 55112

Re: K151523

Trade/Device Name: Uncoated Tubing and Connector Components  
Regulation Number: 21 CFR 870.4210  
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing  
Regulatory Class: Class II  
Product Code: DWF, DTL  
Dated: June 18, 2015  
Received: June 22, 2015

Dear Jacqueline Hauge:

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 "M. D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

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)

K151523

Device Name

Uncoated Tubing and Connector Components

Indications for Use (Describe)

This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgical procedures.

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.\***

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**Date Prepared:** June 4, 2015

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

**Contact Person:** Jacqueline A. Hauge  
Senior Regulatory Affairs Specialist  
Medtronic Perfusion Systems  
Phone: 763.514.9967  
Fax: 763.367.8360  
Email: jacqueline.a.hauge@medtronic.com

**Alternate Contact:**  
Susan Fidler  
Senior Regulatory Affairs Manager  
Medtronic Perfusion Systems  
Phone: 763.514.9839  
Fax: 763.367.8360  
Email: susan.c.fidler@medtronic.com

**Device Name and Classification**

**Trade Name:** Uncoated Tubing and Connector Components

**Regulation Name:** Cardiopulmonary bypass vascular catheter, cannula, or tubing

**Regulation Number:** 21 CFR 870.4210

**Product Code:** DWF, DTL

**Regulatory Class:** Class II

**510(k) Review Panel:** Cardiovascular

**Predicate Devices**

**K113845** Tubing, Connectors and Accessories with Balance Biosurface

**K122811** Connector Components with Balance Biosurface

## **Device Description**

Medtronic uncoated Tubing and Connector Components are intended for use in the extracorporeal circuit during cardiopulmonary bypass surgery. These components are primarily used to interconnect the primary devices of the bypass circuit. The lumen of the uncoated Tubing and Connector Components consist of smooth blood-contacting surfaces which provide a continuous pathway for the flow of blood and/or other fluids during cardiopulmonary bypass surgical procedures. The uncoated Tubing Components are comprised of polyvinyl chloride (PVC) and the uncoated Connector Components are comprised of polycarbonate and Plasticsol. The uncoated Connectors are provided in Y-type, straight, and reducer configurations with 1/8 inch to 1/2 inch connection sites.

## **Indications for Use**

This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgical procedures.

## **Comparison to Predicate**

When compared to the predicate devices, the uncoated Tubing and Connector Components have the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Base materials
- Packaging materials and configurations
- Method of sterilization and sterility assurance level
- Shelf life

## **Summary of Performance and Biological Testing**

Medtronic conducted the following performance testing for the uncoated Tubing and Connector Components:

- Pressure Integrity
- Pressure Decay
- Pull Force
- Kink Resistance
- Spallation
- Blood Trauma

Additionally, biocompatibility testing was performed in accordance with EN ISO 10993-1:2009 Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process.

Performance and biological tests confirm that the uncoated Tubing and Connector Components met pre-determined acceptance criteria and are substantially equivalent to the predicate device.

## **Conclusion**

Medtronic has demonstrated that uncoated Tubing and Connector Components for use in extracorporeal cardiopulmonary bypass perfusion systems (tubing sets/packs) are substantially equivalent to the predicate devices based upon design, test results, and indications for use. The fundamental scientific principle, labeling and intended use are unchanged from the predicate devices.