K012538

AUG 2 3 2001

Summary of Safety and Effectiveness

Company and Contact Person

Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Tel: 763-391-9183
Fax: 763-391-9603

Marie Holm, Associate Product Regulations Manager, Regulatory Affairs

Device Name

Tubing and Connectors with Trillium™ Biopassive Surface

Name of Predicated or Legally Marketed Device

Intersept Blood Tubing Packs (K800178)
Affinity Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

Description of Device

The tubing consists of biocompatible polyvinyl chloride tubing in various lengths (see Appendix I). This tubing will be used in the extracorporeal circuit during cardiopulmonary bypass to interconnect the catheters and cannula with an oxygenator and other accessory bypass equipment.

The connectors consist of molded fittings for use in interconnecting tubing, cannula and/or other extracorporeal devices (see Appendix I).

Tubing and connectors are coated with Trillium™ Biopassive Surface (a polymer containing non-leaching heparin).

Statement of Intended Use

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

Statement of Intended Use of Predicate Device

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

Statement of Technological Characteristics and Comparison

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

Determination of Substantial Equivalence

This **"SPECIAL 510(k)"** is being submitted for a modification to various Medtronic tubing and connectors. The modification to the current tubing and connectors is to coat the blood contact surfaces with Trillium™.

The Medtronic Tubing and Connectors with Trillium™ Biopassive Surface are being compared to the following marketed devices:

Tubing and connectors described in (K800178)
Affinity Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

The tubing and connectors with Trillium™ Biopassive Surface have the same indications statement and intended uses as the:

Tubing and connectors described in (K800178)

The tubing and connectors with Trillium™ Biopassive Surface have no "new technological characteristics (e.g., materials and manufacturing processes)" from the currently marketed tubing and connectors.

The technological characteristic of the Trillium™ Biopassive Surface is used in other cardiopulmonary devices currently in commercial distribution as follows:

Affinity Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "new technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the tubing and connectors with Trillium™ Biopassive Surface are substantially equivalent to other marketed tubing and connectors.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the tubing and connectors with Trillium™ Biopassive Surface does not significantly affect safety and effectiveness and are substantially equivalent to other

commercially distributed cardioplegia delivery system. The *in vitro* bench testing included analysis of:

Coating Characteristics:

Coating
Leaching

Physical/Performance Characteristics:

Spallation
Pressure Decay/Pressure Integrity
Kink Resistance
Blood Trauma
Pull Strength

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Ms. Marie Holm
Associate Product Regulations Manager
Medtronic, Inc.
7611 Northland Drive
Minneapolis, MN 55428

Re: K012538
Tubing and Connectors with Trillium™ Biopassive Surface
Regulation Number: 870.4210
Regulatory Class: II (two)
Product Code: DWF
Dated: August 6, 2001
Received: August 7, 2001

Dear Ms. Holm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number if known: K012538

Device Name: Medtronic Tubing and Connectors with Trillium™ Biopassive Surface

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012538

Prescription Use ✓ OR Over-the-Counter Use ___

Per 21 CFR 801.109