

SEP 14 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 L. Holm, Associate Product Regulations Manager, Regulatory Affairs

**DEVICE NAME**

Trillium™ Bio-Probe Disposable Blood Flow Probe

**NAME OF PREDICATED OR LEGALLY MARKETED DEVICE**

Bio-Probe Disposable Blood Flow Probe (K830858)  
AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

**DESCRIPTION OF DEVICE**

The Trillium™ Bio-Probe Disposable Blood Flow Probe is a single-use insert designed to be used in the Bio-Probe Blood Flow Monitoring System.

**STATEMENT OF INTENDED USE**

The Trillium™ Bio-Probe Disposable Blood Flow Probe is a single-use insert designed to be used in the Bio-Probe Blood Flow Monitoring System.

The Bio-Probe Blood Flow Monitoring System is to be used with an appropriate model Bio-Console to measure directly the blood flow in the extracorporeal perfusion circuit.

**STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE**

The Bio-Probe Disposable Blood Flow Probe is a single use insert designed to be used in the Bio-Probe Blood Flow Monitoring System.

The Bio-Probe Blood Flow Monitoring System is to be used with an appropriate model Bio-Console to measure directly the blood flow in the extracorporeal perfusion circuit.

**STATEMENT OF TECHNOLOGICAL CHARACTERISTICS 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 the Bio-Probe Disposable Blood Flow Probe. The modification to the current Bio-Probe Disposable Blood Flow Probe is to coat the blood contact surfaces with Trillium™.

The Trillium™ Bio-Probe Disposable Blood Flow Probe is being compared to the following Marketed Devices:

- Bio-Probe Disposable Blood Flow Probe (K830858)
- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

The Trillium™ Bio-Probe Disposable Blood Flow Probe has the same indications statement and intended uses as the:

- Bio-Probe Disposable Blood Flow Probe (K830858)

The Trillium™ Bio-Probe Disposable Blood Flow Probe has “no new technological characteristics (e.g., materials and manufacturing processes)” from the Bio-Probe Disposable Blood Flow Probe. The technological characteristic is solely the coating material of the blood pathway:

- Trillium™

The technological characteristic of the Trillium™ Biopassive Surface is common to other medical devices (hollow fiber oxygenators) 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 “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 Trillium™ Bio-Probe Disposable Blood Flow Probe is substantially equivalent to other marketed extracorporeal cardiopulmonary devices.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Trillium™ Bio-Probe Disposable Blood Flow Probe does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed extracorporeal cardiopulmonary devices. The *in vitro* bench testing included analysis of:

- Coating Characteristics
- Physical Characteristics
- Performance Characteristics



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Marie L. Holm  
Medtronic Perfusion Systems  
7611 Northland Drive N  
Minneapolis, MN 55428-1088

Re: K012747

Trade Name: Trillium™ Bio-Probe Disposable Blood Flow Probe (DP38T and DP38PT)  
Regulation Number: 21 CFR 870.2120  
Regulation Name: Extravascular Blood Flow Probe  
Regulatory Class: Class II (two)  
Product Code: DPT  
Dated: August 15, 2001  
Received: August 16, 2001

Dear Ms. Holm:

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.

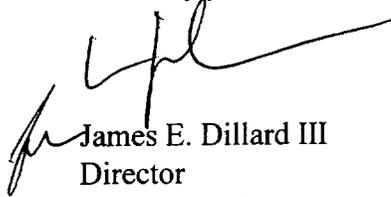
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 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  
Director  
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: K012747 -

**Device Name:** Trillium™ Bio-Probe Disposable Blood Flow Probe

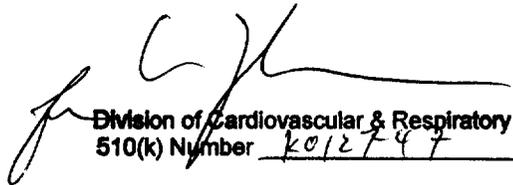
The Trillium™ Bio-Probe Disposable Blood Flow Probe is designed for use in the Bio-Probe Blood Flow Monitoring System.

**Indications for Use:**

The Bio-Probe blood flow monitoring system is to be used with an appropriate model Bio-Console® extracorporeal blood pumping console to measure directly the blood flow in the extracorporeal perfusion circuit.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K012747

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter use