

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**COMPANY AND CONTACT PERSON**

NOV 20 1997

Medtronic, Inc.  
Cardiopulmonary Division  
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Debra J. Kridner, Manager  
Regulatory Affairs

**DEVICE NAME**

CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface

**NAME OF PREDICATE OR LEGALLY MARKETED DEVICE(S)**

- Medtronic CardioTherm™ Blood Cardioplegia Systems (K960755)
- Medtronic Extracorporeal Circuit with Carmeda® BioActive Surface (K891687)
- Medtronic MAXIMA PLUS® PRF Hollow Fiber Oxygenator with Carmeda® BioActive Surface (K941473)

**DESCRIPTION OF DEVICE**

The Medtronic CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface is coated with a non-leaching bioactive heparin surface which provides thromboresistant blood contact surfaces. The Carmeda® BioActive Surface is present on blood path materials.

Each Medtronic CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface is a single use, disposable device designed to mix arterial blood from an oxygenator with asanguineous cardioplegia solution in specific ratios depending on the tubing set configurations. The blood/cardioplegia solution is then cooled/warmed and delivered to the patient.

The Medtronic CardioTherm™ Blood Cardioplegia Heat Exchanger with Carmeda® BioActive Surface consists of a polycarbonate housing which incorporates a bubble chamber. A stopcock is attached to the upper luer port of the housing lid allowing for air venting through a purge line during priming and pressure monitoring through a vented or non-vented pressure monitoring line throughout the procedure. A temperature probe port is located adjacent to the blood outlet port at the bottom of the device, allowing for temperature monitoring of the blood/cardioplegia solution prior to patient delivery.

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The heat exchanger housing contains non-porous polypropylene hollow fibers, which are supported on their exterior by a polyethylene screen. These polypropylene fibers run longitudinally through the polycarbonate chamber. Blood/cardioplegia solution flows through the polypropylene hollow fibers. The walls of these fibers provide a barrier between the blood/cardioplegia solution and the cooling/warming water.

The flow of solution through the Medtronic CardioTherm™ Blood Cardioplegia Heat Exchanger with Carmeda® BioActive Surface is as follows:

#### Blood/Cardioplegia

The blood and/or cardioplegia solution enters the bottom of the device, flows up through the polypropylene hollow fibers, flows back down a center collecting tube, and exits the from the bottom of the device.

#### Water

The cooling/warming water enters a side port, passes around the outside walls of the polypropylene fibers, then exits through a parallel side port.

Heat exchange occurs as the blood/cardioplegia solution passes through the hollow fibers, while the temperature regulated cooling/warming water passes around the outside walls of the same fibers. The blood/cardioplegia solution is cooled/ warmed as it flows through the heat exchanger.

By connecting tubing of specific inner diameters to the heat exchanger, a predetermined approximate ratio of blood to cardioplegia solution may be delivered to the patient. The tubing sets are equivalent to the tubing sets which are currently used for the CardioTherm™ Blood Cardioplegia System (K960755)

Four of the various delivery ratios available are:

1. a tubing set for 1:1 ratio of blood to asanguineous cardioplegia.
2. a tubing set for 2:1 ratio of blood to asanguineous cardioplegia.
3. a tubing set for 4:1 ratio of blood to asanguineous cardioplegia.
4. a tubing set for 9:1 ratio of blood to asanguineous cardioplegia.

These tubing ratios are identical to the commercially available CardioTherm™ Blood Cardioplegia Systems.

### STATEMENT OF INTENDED USE

The Medtronic CardioTherm™ Blood Cardioplegia System, with or without Carmeda® BioActive Surface, is intended for use in procedures requiring the mixing, cooling, warming, and delivery of oxygenated blood and/or asanguineous cardioplegia solution.

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## STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Medtronic CardioTherm™ Blood Cardioplegia System is intended for mixing, cooling, warming, and delivery of oxygenated blood and/or asanguineous cardioplegia solution.

## STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

A table comparing the intended use and technological characteristics of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface with the substantially equivalent device is provided in Attachment 1. In addition, information regarding technological characteristic comparison is provided in the following section, "Determination of Substantial Equivalence".

## DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification is being submitted for a modification to the Medtronic CardioTherm™ Blood Cardioplegia Systems. This modification is for the Carmeda® coating of the Medtronic CardioTherm™ Blood Cardioplegia Systems.

This premarket notification submission provides substantial equivalence information and rationale which addresses the introduction to commercial distribution of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface.

The Medtronic CardioTherm™ Blood Cardioplegia Systems are devices which are currently in commercial distribution. The CardioTherm™ Blood Cardioplegia Systems (K960755) were deemed substantially equivalent to other blood cardioplegia devices on May 23, 1996.

In determining substantial equivalence of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface (further references will state Carmeda® CardioTherm™), the decision-making process follows the 510(k) "Substantial Equivalence" flow diagram and is presented as follows:

The Carmeda® CardioTherm™ is being "compared to the following Marketed Devices":

- Medtronic CardioTherm™ Blood Cardioplegia Systems (K960755)
- Medtronic Extracorporeal Circuit with Carmeda® BioActive Surface (K891687)
- Medtronic MAXIMA PLUS® PRF Hollow Fiber Oxygenator with Carmeda® BioActive Surface (K941473)

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The Carmeda® CardioTherm™ has the “same indications statement and intended uses” as the:

- CardioTherm™ Blood Cardioplegia Systems (K960755)

The Carmeda® CardioTherm™ has “new technological characteristics (e.g., design, materials and manufacturing processes)” from the current Medtronic CardioTherm™ Blood Cardioplegia Systems. These technological characteristics include;

- Carmeda® BioActive Surface
- This technological characteristics is common to other Medtronic Carmeda® coated products currently in commercial distribution as follows;
  - Medtronic Extracorporeal Circuit with Carmeda® Bio-Active Surface (K891687)
  - Medtronic MAXIMA PLUS® PRF Hollow Fiber Oxygenator with Carmeda® BioActive Surface (K941473)

These technological characteristics “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 accepted scientific methods which exist for assessing effects of these new technological characteristics”. These scientific methods are identical to the method used for other Medtronic Carmeda® coated products.

“Performance data to assess the effects of these new technological characteristics” has been obtained through in-vitro bench testing. These “performance data demonstrate” that the CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface are substantially equivalent to marketed devices.

In addition, the modes of operation of the CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface are either identical or substantially equivalent to other blood cardioplegia systems in commercial distribution. The function of the Medtronic CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface is mixing, cooling, warming, and delivery of oxygenated blood and/or asanguineous cardioplegia solution.

A table comparing the intended use, performance characteristics, technological characteristics and mode of operation of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface with the noted substantially equivalent device is provided in Attachment 1.

These data support that the blood cardioplegia systems with Carmeda® BioActive Surface do not significantly affect safety and effectiveness and are substantially equivalent to another commercially distributed blood cardioplegia system.

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The biocompatibility testing and in-vitro bench testing demonstrated that when compared to the predicate devices the CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive Surface do not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed devices. The in-vitro bench testing included analysis of:

- Carmeda® Performance Characteristic Testing
  - Bioactivity
  - Coating Coverage
  - Leaching
- Performance Characteristic Testing
  - Pressure Drop
  - Blood Trauma
  - Heat Exchange Performance
- Physical Characteristic Testing
  - Physical Integrity
    - Blood Pathway
    - Heat Exchanger Water Pathway
  - Priming Volume

These data support that the blood cardioplegia systems with Carmeda® BioActive Surface do not significantly affect safety and effectiveness and are substantially equivalent to another commercially distributed blood cardioplegia system.

**Attachment 1**

**DEVICE COMPARISONS – GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS**

	<b>Medtronic, Inc. CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface</b>	<b>Medtronic, Inc. CardioTherm™ Blood Cardioplegia System</b>
<b><u>510(k) Number:</u></b>	This submission	K960755
<b><u>Catalog Number(s):</u></b>	CBCT-XXX Series CBCT-XXXBR Series	CT-XXX Series CT-XXXBR Series
<b><u>Intended Use:</u></b>	To mix, cool, warm and deliver oxygenated blood/cardioplegia solution.	To mix, cool, and deliver oxygenated blood/cardioplegia solution.
<b><u>Performance Characteristics:</u></b>		
<b>Heat Exchanger</b>		
Priming Volume (ml)	46	46
Maximum Flow Rate (lpm)	1	1
Fluid Path Pressure (max)	500 mmHg	500 mmHg
Water Path Pressure (max)	45 psi	45 psi
<b><u>Technological Characteristics:</u></b>		
<b>Configuration</b>		
Heat Exchanger	Yes	Yes
Vent Port	Yes	Yes
Bubble Chamber	Yes	Yes
Temperature Well	Yes	Yes
Pressure Monitoring Line	Yes	Yes
Patient Delivery Line	Yes	Yes
Tubing Sets	Yes	Yes
<b>Materials</b>		
<b>Heat Exchanger</b>		
Housing	Polycarbonate	Polycarbonate
Heat Exchanger	Polypropylene	Polypropylene
<b>Tubing Sets</b>		
	Polyvinyl chloride Polycarbonate	Polyvinyl chloride Polycarbonate
<b>Carmeda® BioActive Surface*</b>	Yes	No

\* Carmeda® Bioactive Surface has been used on Medtronic Cardiopulmonary devices since 1989. (K891687 - Medtronic Extracorporeal Circuit with Carmeda® BioActive Surface).

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**APPENDIX IV**

**Attachment 1**

**DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS**

<b>Specifications</b>	<b>Medtronic, Inc. CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface</b>	<b>Medtronic, Inc. CardioTherm™ Blood Cardioplegia System</b>
<b>Tubing Set Ratios</b>	Separate sets (1:1, 2:1, 4:1 and 9:1)	Separate sets (1:1, 2:1, 4:1 and 9:1)
<b>Tubing Inner Diameter</b>	1/12 inch to 1/4 inch	1/12 inch to 1/4 inch
<b>Ratio Capability</b>	Variable (w/bridge clamps) (all blood, 1:1, 2:1, 4:1, 9:1, and all crystalloid with various tubing sets)	Variable (w/bridge clamps) (all blood, 1:1, 2:1, 4:1, 9:1, and all crystalloid with various tubing sets)
<b>Mode of Operation</b>	This blood/cardioplegia system is used in the extracorporeal circuit for mixing, cooling, warming and delivery of oxygenated blood and/or cardioplegia solution. The multiple configurations allow the clinician the capability of providing varying ratios of blood to cardioplegia solution as warranted by clinical need.	This blood/cardioplegia system is used in the extracorporeal circuit for mixing, cooling, warming and delivery of oxygenated blood and/or cardioplegia solution. The multiple configurations allow the clinician the capability of providing varying ratios of blood to cardioplegia solution as warranted by clinical need.

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Rockville MD 20857

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Sr. Manager, Regulatory Affairs/Clinicals  
Cardiac Surgery  
Medtronic, Inc.  
Cardiopulmonary Division  
4633 East La Palma Avenue  
Anaheim, California 92807

NOV 20 1997

Re: K973475  
CardioTherm™ Blood Cardioplegia Systems with Carmeda® BioActive  
Surface  
Regulatory Class: II (Two)  
Product Code: 74 DTR  
Dated: September 10, 1997  
Received: September 12, 1997

Dear Ms. Kridner:

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 to 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) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, stylized initial 'T'.

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

### INDICATIONS FOR USE

510(k) Number: K973475

Device Name: **CardioTherm™ Blood Cardioplegia System with Carmeda® BioActive Surface**

**Indications for use:**

The Medtronic CardioTherm™ Blood Cardioplegia System, with or without Carmeda® BioActive Surface, is intended for use in procedures requiring the mixing, cooling, warming, and delivery of oxygenated blood and/or asanguineous cardioplegia solution.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

*Patricia L. Campbell*  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K973475

Prescription Use X OR Over-The-Counter-Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)