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SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

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DEVICE NAME

CardioTherm™ Blood Cardioplegia Delivery Systems
(CTXXX Series and CTXXXBR Series)

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

- Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems (K934355)
- Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems (K896807/ K944219)
- Avecor Cardiovascular - MYOtherm™ Cardioplegia Delivery Systems (K904171)
- Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System (K925369)

DESCRIPTION OF DEVICE

Each Medtronic CardioTherm™ Blood Cardioplegia System 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™ Cardioplegia Heat Exchanger 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 nonvented 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.

The heat exchanger housing contains nonporous 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 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 manufactured with polyvinyl chloride tubing and polycarbonate/polyvinyl chloride connectors which are currently used as components in the commercially distributed Medtronic Extracorporeal InterSept™ Custom Tubing Packs (K800178) and Medtronic InterSept™ Crystalloid Cardioplegia Delivery System (K885154). 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 common to commercially available blood cardioplegia systems; including the Medtronic Electromedics, Inc. Blood Cardioplegia Delivery Systems, the Gish Biomedical, Inc. Single Pass Blood Cardioplegia (SPBC) Systems, the Avecor Cardiovascular MYOtherm™ Cardioplegia Delivery Systems and the Sorin Biomedical BCD ADVANCED Blood Cardioplegia System.

Tubing inner diameters for commercially available tubing sets generally range from 3/32" (2.4 mm) to 17/64" (6.7mm).

STATEMENT OF INTENDED USE

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

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems are intended to mix, cool, and deliver oxygenated blood/cardioplegia solution in a predetermined ratio.

The Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems are intended to mix, cool/warm, and deliver oxygenated blood/cardioplegia solution.

The Avecor Cardiovascular - MYOtherm™ Cardioplegia Delivery Systems are intended to mix, cool, and deliver oxygenated blood/cardioplegia solution in a predetermined ratio.

The Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System are intended to mix, cool/warm, and deliver oxygenated blood/cardioplegia solution.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

A table comparing the intended use and technological characteristics of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems with the four noted substantially equivalent devices is provided in Attachment I.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification submission provides substantial equivalence information and rationale which addresses the introduction to commercial distribution of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia System.

The Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems are substantially equivalent to other Blood Cardioplegia Systems currently in commercial distribution. These predicate/marketed devices include:

- Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems (K934355)
- Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems (K896807/ K944219)
- Avecor Cardiovascular - MYOtherm™ Cardioplegia Delivery Systems (K904171)
- Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System (K925369)

The Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems have an intended use which is substantially equivalent to other Blood Cardioplegia Systems currently in commercial distribution. These predicate/marketed devices include:

- Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems (K934355)
- Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems (K896807/ K944219)
- Avecor Cardiovascular - MYOthem™ Cardioplegia Delivery Systems (K904171)
- Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System (K925369)

The Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems have technological characteristics which are substantially equivalent to other Blood Cardioplegia Systems currently in commercial distribution. These predicate/marketed devices include:

- Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems (K934355)
- Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems (K896807/ K944219)
- Avecor Cardiovascular - MYOthem™ Cardioplegia Delivery Systems (K904171)
- Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System (K925369)

The design, construction, materials and nominal specifications of the Medtronic Cardiopulmonary CardioTherm™ Blood Cardioplegia Systems are either identical or substantially equivalent to other Blood Cardioplegia Systems currently in commercial distribution. These predicate/marketed devices include:

- Medtronic Electromedics, Inc. - Blood Cardioplegia Delivery Systems (K934355)
- Gish Biomedical, Inc. - Single Pass Blood Cardioplegia (SPBC) Systems (K896807/K944219)
- Avecor Cardiovascular - MYOthem™ Cardioplegia Delivery Systems (K904171)
- Sorin Biomedical - BCD ADVANCED Blood Cardioplegia System (K925369)

DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS

	Medtronic, Inc. CardioTherm™ Blood Cardioplegia System	Medtronic, Inc./Electromedics Inc. Blood Cardioplegia. Delivery Systems	Gish Biomedical, Inc. SPBC Blood Cardioplegia Systems	Avecor Cardiovascular MYOTherm™ Cardioplegia Delivery Systems	Sorin Blomdical BCD ADVANCED™ Blood Cardioplegia System
510(k) Number:	This submission	K934355	K896807	K904171	K925369
Catalog Number(s):	CT-XXX Series CT-XXXBR Series	D1081A, D1080A, D1082A	SPBC-XX Series SPBC-XXXBR Series	MYOTherm™ XX Series MYOTherm™ XX BR Series	BCD ADV X Series (includes bridge/shunt system)
Intended Use:	To mix, cool, warm and deliver oxygenated blood/cardioplegia solution.	To mix, cool, and deliver oxygenated blood/cardioplegia solution in a predetermined ratio.	To mix, cool/warm, and deliver oxygenated blood/cardioplegia solution.	To mix, cool, and deliver oxygenated blood/cardioplegia solution in a predetermined ratio.	To mix, cool/warm, and deliver oxygenated blood/cardioplegia solution.
Performance Characteristics:					
Heat Exchanger					
Priming Volume (mL)	46	55	83	68	55
Maximum Flow Rate (LPM)	1	3	not rated	not rated	.5
Fluid Path Pressure (maximum)	500 mmHg	not rated	300 mmHg	500 mmHg	not rated
Water Path Pressure (maximum)	45 psi	45 psi	65psi	40 psi	80 psi
Technological Characteristics:					
Configuration	Heat Exchanger	Heat Exchanger	Heat Exchanger	Heat Exchanger	Heat Exchanger
Heat Exchanger					
Vent Port	Yes	Yes	Yes	Yes	Yes
Bubble Chamber	Yes	Yes	Yes	Yes	Yes
Temperature Well	Yes	Yes	Yes	Yes	Yes
Pressure Monitoring Line	Yes	Yes	Yes	Yes	Yes
Patient Delivery Line	Yes	Yes	Yes	Yes	Yes
	Various Tubing Sets	Various Tubing Sets	Various Tubing Sets	Various Tubing Sets	Various Tubing Sets

DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS

	Medtronic, Inc. CardioTherm™ <u>Blood Cardioplegia System</u>	Medtronic, Inc./Electromedics Inc. Blood Cardioplegia. <u>Delivery Systems</u>	Gish Biomedical, Inc. SPBC <u>Blood Cardioplegia Systems</u>	Avecor Cardiovascular MYOTherm™ <u>Cardioplegia Delivery Systems</u>	Sorin Biomedical BCD ADVANCED <u>Blood Cardioplegia System</u>
Materials					
Heat Exchanger Housing Heat Exchanger	Polycarbonate Polypropylene	Polycarbonate Stainless steel	Polycarbonate Aluminum	Polycarbonate Stainless steel	Polycarbonate Aluminum
Tubing Sets	Polyvinyl chloride Polycarbonate				
Specifications					
Tubing Set Ratios	Separate sets (1:1, 2:1, 4:1 and 9:1)	Separate sets (1:1, 2:1 and 4:1)	Separate sets (1:1, 2:1, 4:1 and 9:1)	Separate sets (1:1, 2:1, 4:1 and 9:1)	Separate sets (1:1, 2:1, 4:1 and 8:1)
Tubing Inner Diameter	1/12 inch to 1/4 inch	1/8 inch to 1/4 inch	3/32 inch to 17/64 inch	1/8 inch to 1/4 inch	3/32 inch to 17/64 inch
Ratio Capability	Variable (w/bridge clamps) (all blood, 1:1, 2:1, 4:1, 9:1, and all crystalloid with various tubing sets)	Variable (1:1, 2:1 and 4:1)	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)	Variable (w/bridge clamps) (all blood, 1:1, 2:1, 4:1, 8:1, and all crystalloid with various tubing sets)
Mode of Operation	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 based on the patients' 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 based on the patients' 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 based on the patients' 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 based on the patients' 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 based on the patients' clinical need.