K973237

APR 27 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

COMPANY AND CONTACT PERSON

Medtronic Bio-Medicus, Inc.
Cardiopulmonary Division
9600 West 76th Street
Eden Prairie, MN 55344
tel. (612)944-7784
fax (612)944-7557

Thomas K. Johnsen
Product Regulations Manager

TRADE NAME

CSS™ Cardioplegia Safety System Model 990.

COMMON, USUAL OR CLASSIFICATION NAME

The devices which comprise the CSS™ Cardioplegia Safety System have been classified by the Cardiovascular Device Classification Panel as Class II devices.

21 CFR 870.4370 Roller type cardiopulmonary bypass blood pump
21 CFR 870.4240 Cardiopulmonary bypass heat exchanger
21 CFR 870.4390 Cardiopulmonary bypass pump tubing

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Sorin Biomedical Inc. - Sorin Blood Cardioplegia Console (K942582)
Quest Medical Inc. - Myocardial Protection System (K953838)
Sarns Inc/3M - Sarns 9000 Heart Lung Console (K871131)
Medtronic, Inc. Cardiopulmonary - CardioTherm™ Blood Cardioplegia Delivery System (K960755)

DESCRIPTION OF DEVICE

The Medtronic CSS™ Cardioplegia Safety System Model 990 consists of an electro-mechanical instrument and disposable Cardioplegia Sets. The details of these components are described below.

Instrument: CSS™ Cardioplegia Safety System Model 990

Peristaltic Pumps:

The CSS™ Instrument delivers cardioplegia solution to the patients myocardium through a system of dual peristaltic independently operated pumps. One pump is dedicated for the delivery of blood, and the other pump is dedicated for the delivery of crystalloid solution. The dual roller pumps feature interlocks so that the disposable tubing sets can only be loaded one way. Each roller pump is designed with a mechanically spring loaded back to maintain constant pressure on the tubing (ensures flow accuracy). The spring loaded feature also allows the mechanical release of fluid pressure in the case of over pressurization . The pump mechanism will not generate a line pressure greater than 1200 mmHg. To ensure patient safety, the microprocessor will shut the unit down if the line pressure or external pressure exceeds 500 mmHg. The user may also set the pressure limits at values less than 500 mmHg which will alarm, and shut the unit down. Each roller pump head is equipped with an air detection transducer which uses ultrasonic detection technology that will detect gross air (air bubble of at least 1/4" diameter) entering the inlet side of each roller pump. This feature is used to alert the user of an empty cardioplegia bag, low fluid or no fluid conditions entering the roller pump.

Volume:

Cardioplegia solution can be delivered to the patient at a controlled volume by selecting the relative pump speed for the ratio of blood to cardioplegia solution.

The CSS™ Instrument monitors the volume of solution delivered. During typical clinical procedures, cardioplegia is delivered in phases. Therefore, the CSS™ instrument provides two volume counters. The function of these counters is as follows:

1. One volume counter reports the volume delivered during individual phases of operation. This counter can be reset to zero after each phase.
2. The other volume counter records and reports the total volume delivered for all phases of operation.

A total volume limit can be set by the user. If the total volume limit is exceeded then an alert condition is triggered.

Flow Rate:

The CSS™ Instrument is able to control solution flow rate by flow and by pressure. Solution flow rate is controlled by direct adjustment of the flow control knob (Manual mode), or the CSS™ can deliver solution by a user-defined constant pressure setting (Constant pressure mode). The flow rate can be adjusted from 0 - 990 ml/min.

Ratios:

Based on the patient's clinical need the ratio of blood to cardioplegia solution may vary (1:0, 1:1, 2:1, 3:1, 4:1, 5:1, 6:1, 7:1, 8:1, 9:1, & 0:1, 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9). Alternative blood-to-cardioplegia ratios may be made available, as warranted by clinical need. A Protocol mode of operation allows the user to customize and store up to 9 distinct cardioplegia protocols; protocol settings can be changed as determined by the user needs.

Temperature Monitoring:

When monitoring temperature of the cardioplegia heat exchanger, use a Medtronic Probe, Model 1384 which contains a YSI 400 Thermistor. If monitoring of the myocardium is desired, a Medtronic Blood Management Myocardial Needle Temperature Probe must be used. Two myocardial needles are available. The 2100 series Myocardial Needle requires the #9012-147T adapter, and the 2400 series Myocardial Needle requires the #9004 adapter.

Pressure Monitoring:

The CSS™ Instrument monitors pressure at two sites;

1. at the CSS™ Instrument - line pressure, and
2. at the cannulae - external pressure

Separate alert and alarm levels can be setup by the user for each of these sites.

Gross Air Detector:

Each roller pump head is equipped with an air detection transducer which uses ultrasonic detection technology that will detect gross air (air bubble of at least 1/4" diameter) entering the inlet side of each roller pump. This feature is used to alert the user of an empty cardioplegia bag, low fluid or no fluid conditions entering the roller pump.

Timers:

The CSS™ Instrument is also equipped with two independent elapsed timers to assist the operator in the management of cardioplegia delivery. One timer is typically used to monitor cross-clamp duration, and one timer is typically used to monitor cardioplegia delivery duration. The timers can be reset at any time for use in other applications.

Central Information Display:

The color central information display (CID) provides a constant indication of the instrument's operating state. Key-pad buttons adjacent to the display are used for setting adjustable parameters. The display shows running totals of solution volumes infused and provides both numeric and bar graph representation of

pressure in mmHg or kPa. A configuration screen allows the user to select the language shown on the display, as well as the pressure measurement units, and the alarm tone.

Alarms and Alerts:

Safety features have been designed into the CSS™ Instrument by initial power on and continual run-time software tests. The CSS™ Instrument has a two stage alert-alarm process. Alarms and alerts are presented both visually and audibly. If an alarm condition exists, the unit will automatically shut the roller pumps off until the alarm state is corrected.

Battery:

Battery operation, is automatically enabled in the case of AC power failure. This feature offers 60 minutes of "On" time (displays, and monitors), and 15 minutes of pumping time. The 15 minutes pumping time is the typical time of cardioplegia delivery during bypass surgery.

Hardware:

The CSS™ can be mounted in most conventional heart-lung systems, with the exception of heart-lung machines that require common air flow for the cooling of each module. The CSS™ can also be mounted on a 1.00" to 1.75" diameter horizontal pole. An adapter is provided for vertical pole mounting.

Instrument Accessory

The Graseby Medical Ltd., Model 3400 Anesthesia Syringe Pump 510(k) # K931318 can be connected to the CSS™ Cardioplegia Safety System Model 990 by way of an RS232 port for administration of arresting agents (e.g. potassium).

Disposables

CSS™ Cardioplegia Sets

The Medtronic® CSS™ Cardioplegia Sets are designed to work specifically with the Medtronic® CSS™ Cardioplegia Safety System, Model 990 instrument.

The CSS™ Cardioplegia Sets are single use, sterile and nonpyrogenic disposable devices designed to mix arterial blood from the cardiopulmonary bypass circuit with asanguineous cardioplegia solution at a variety of ratios, depending on clinical need. The CSS™ set is available in four configurations as follows:

1. With CardioTherm™ Heat Exchanger and Standard patient line

2. With CardioTherm™ Heat Exchanger and Dual Lumen patient line

3. With Standard patient line - No CardioTherm™ Heat Exchanger

4. With Dual Lumen patient line - No CardioTherm™ Heat Exchanger

The components used in the CSS™ Cardioplegia Sets are identical to the components used in the currently marketed CardioTherm™ Blood Cardioplegia Systems (K960755). There are only two modifications to the CardioTherm™ Blood Cardioplegia System tubing sets. These modifications are:

1) silicone tubing set (with connectors) will be used as the pump header tubing, instead of polyvinyl chloride, and
2) the patient line can be either dual or single lumen, instead of just single lumen.

The CardioTherm™ Blood Cardioplegia Systems are currently manufactured, packaged and sterilized by Medtronic Cardiopulmonary, Anaheim, CA. The CSS™ Cardioplegia Sets will be manufactured, packaged and sterilized by Medtronic Cardiopulmonary, Anaheim, CA.

Silicone Tubing and Polycarbonate Connectors

Each CSS™ Cardioplegia Set will include medical grade silicone tubing with polycarbonate connectors to facilitate the insertion of the tubing into the roller pump head. Silicone tubing offers two distinctive advantages over polyvinyl chloride tubing when used in the roller pump. These advantages are:

1. Less temperature sensitivity which offers more consistent and accurate flow (the pliability of polyvinyl chloride tubing tends to be affected by temperature change),

2. Allows measurement of line pressure through the silicone tubing by means of the line pressure transducers mounted in the roller pump. This eliminates the need for additional in-line components.

The internal diameter of the CSS™ Cardioplegia Set silicone pump header tubing will not vary since the blood to solution ratios are controlled by the speed of the roller pumps.

Dual Lumen Patient Line

The dual lumen patient line is identical in material composition to the standard lumen patient line. The dual lumen patient line is tubing extruded with two separate lumens, one for the cardioplegia delivery, and the other for external pressure monitoring.

INTENDED USE OF THE DEVICE

The Medtronic CSS™ Cardioplegia Safety System is intended for use as a cardioplegia delivery system which controls, monitors, and delivers oxygenated blood and/or asanguineous solutions during cardiopulmonary bypass procedures.

INTENDED USE OF PREDICATE/MARKETED DEVICES

Sorin Blood Cardioplegia Console ("BCC")
The Sorin Blood Cardioplegia Console ("BCC") is intended for use by qualified personnel during cardiopulmonary bypass procedures to control and monitor the introduction of blood and/or crystalloid in the management of cardioplegia.

Quest MPS Myocardial Protection System
The Quest MPS myocardial protection system is intended for use by perfusionists and surgeons trained in delivering cardioplegia solution to the myocardium during open heart surgery

Sarns 9000 Perfusion System
The Sarns 9000 Perfusion System is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment. With Cardioplegia Control Module installed, the 9000 system is indicated to pump a set volume of cardioplegia fluid at a set pressure during cardiopulmonary bypass procedures.

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

SUBSTANTIAL EQUIVALENCE

The Medtronic CSS™ Cardioplegia Safety System is substantially equivalent to other cardioplegia systems currently in commercial distribution. These predicate/marketed devices include:

Sorin Biomedical - (BCC) - Blood Cardioplegia Console (K942582)
Quest Medical Inc. - (MPS) - Myocardial Protection System (K953838)
Sarns/3M - Sarns 9000 Heart Lung Console (K871131)
Medtronic, Inc. Cardiopulmonary - CardioTherm™ Blood Cardioplegia Delivery System (K960755) - Disposable component only

In determining substantial equivalence of the CSS™ Cardioplegia Safety System, the decision-making process follows the 510(k) **"Substantial Equivalence"** flow diagram, and is presented as follows:

The CSS™ Cardioplegia Safety System is being **"compared to the following Marketed Devices":**

- Sorin Biomedical - (BCC) - Blood Cardioplegia Console (K942582)
- Quest Medical Inc. - (MPS) - Myocardial Protection System (K953838)
- Sarns/3M - Sarns 9000 Heart Lung Console (K871131)
- CardioTherm™ Blood Cardioplegia Delivery System (K960755)

The CSS™ Cardioplegia Safety System has the **"same indications statement and intended use"** as the predicate/marketed devices

CSS™ Cardioplegia Safety System
The Medtronic CSS™ Cardioplegia Safety System is intended for use as a cardioplegia delivery system which controls, monitors, and delivers oxygenated blood and/or asanguineous solutions during cardiopulmonary bypass procedures.

Sorin Blood Cardioplegia Console ("BCC")
The Sorin Blood Cardioplegia Console ("BCC") is intended for use by qualified personnel during cardiopulmonary bypass procedures to control and monitor the introduction of blood and/or crystalloid in the management of cardioplegia.

Quest MPS Myocardial Protection System
The Quest MPS Myocardial Protection System is intended for use by perfusionists and surgeons trained in delivering cardioplegia solution to the myocardium during open heart surgery

Sarns 9000 Cardioplegia Control Module
The Sarns 9000 Perfusion System is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment.

With Cardioplegia Control Module installed, the 9000 system is indicated to pump a set volume of cardioplegia fluid at a set pressure during cardiopulmonary bypass procedures.

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

The CSS™ Cardioplegia Safety System has **"new technological characteristics (e.g., design, materials and manufacturing processes)"** from the predicate/marketed devices. Similar technological characteristics include;

- pump cardioplegia solutions at specified flow rates by varying the speed of the pump
- measure and display temperature (2)
- measure and display pressure (2)

Additional technological characteristics are provided in the Designed Specification and Design Features Tables.

Like the Quest MPS Myocardial Protection System, the CSS™ Cardioplegia Safety System allows the user to introduce arresting agents (e.g. potassium) into the cardioplegia circuit at specified

flow rates. The CSS™ Cardioplegia Safety System does not offer a built in heater/cooler like the predicate/marketed devices, however, if heating and cooling of the cardioplegia solution is desired, an additional water line can be connected from the CardioTherm™ heat exchanger to the heater/cooler used in the extracorporeal bypass circuit. This is a standard practice commonly used for this application.

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".**

"Performance data to assess the effects of these new technological characteristics" has been summarized below. These **"performance data demonstrate"** that the CSS™ Cardioplegia Safety System is substantially equivalent to marketed devices.

SUMMARY OF TESTING PERFORMED

In-Vitro Bench Testing:

In-vitro bench testing was performed to ensure the CSS™ Cardioplegia Safety System operated in accordance with Medtronic Bio-Medicus device specifications, and in accordance with applicable established standards to ensure user and patient safety. These tests included:

- The CSS™ Instrument Disposable Set Integrity Test
- Pump Flow Performance
- Blood Trauma Test
- Disposable Pressure Drop
- Occlusion and Maximum Pressure
- Constant Pressure Mode Performance
- Line Pressure Measurement System Performance
- External Pressure Measurement
- Gross Air Detection
- Disposable Chemical Resistance
- Temperature Monitoring
- Environmental Testing
- Battery Back-up
- Syringe Pump Performance Test
- Auxiliary Output and Overcurrent Protection
- ESD Testing
- EMI/EMC Immunity & Emissions Testing
- Dielectric and Chassis Leakage Test

Biocompatibility Testing:

The roller pump silicone tubing and polycarbonate connectors are the only components of the disposable set that are not currently marketed components in the CardioTherm™ Blood Cardioplegia Systems (K960755). These materials are however commonly used in the medical industry for various applications, including blood contact devices. These devices were tested in

accordance with the FDA Blue Book Memorandum - #G95-1, and Biological Evaluation of Medical Devices Guidance - International Standard ISO 10993-1 "External Communicating Devices, Circulating Blood" - Contact Duration of A - limited ≤ 24 hours, and in accordance with United States Pharmacopoeia - XXIII.

Based on the results of the biocompatibility testing performed, the materials used were determined to be biocompatible and nontoxic and, therefore, safe for their intended use.

Sterilization:

The CSS™ Cardioplegia Sets will be sterilized in accordance with a validated 100% (EtO) ethylene oxide sterilization method at a minimum sterility assurance level (SAL) of 10^{-6}. The EtO sterilization process procedures, process qualifications and validation are in accordance with criteria described in the American National Standards Institute, Inc. (ANSI) standard ANSI/AAMI/ISO 11135-1994 (Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization).

EtO Residuals:

EtO dissipation curves have been developed and will apply to routine product release to assure that all products meet the limits for residual concentrations of ethylene oxide and ethylene chlorohydrin, and ethylene glycol as published in ANSI Standard Number ANSI/AAMI/ISO 10993-7:1995 (Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals).

Pyrogen Testing:

Routine Pyrogen Testing will be performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than .5 EU/ml) is in accordance to the December, 1987 Guidelines issued by the Food and Drug Administration, Office of Compliance ("Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

CONCLUSION

Based on the information presented above, the CSS™ Cardioplegia Safety System demonstrates substantial equivalence to the predicate/marketed devices, and the CSS™ Cardioplegia Safety System is safe for its intended use.

COMPARISON OF DESIGN SPECIFICATION

Feature	Medtronic CSS	Sorin BCC	Quest MPS	Sarns 9000
Intended Use:	The Medtronic CSS™ Cardioplegia Safety System is intended for use as a cardioplegia delivery system which controls, monitors and delivers oxygenated blood and/or asanguineous solutions during cardio-pulmonary bypass procedures.	The Sorin Blood Cardioplegia Console ("BCC") is intended for use by qualified personnel during cardiopulmonary bypass procedures to control and monitor the introduction of blood and/or crystalloid in the management of cardioplegia.	The Quest MPS Myocardial Protection System is intended for use by perfusionists and surgeons trained in delivering cardioplegia solution to the myocardium during open heart surgery	With Cardioplegia control Module installed, the 9000 system is indicated to pump a set volume of cardioplegia fluid at a set pressure during cardio-pulmonary bypass procedures.
Power	110/220 VAC 50-60 Hz	115 VAC 60 Hz	110/220 VAC 50-60 Hz	115/220 VAC 50-60 Hz
Power Accuracy	+/- 10%	94-128 VAC	not available	103-126V
Pressure Range	0-500 mmHg	0-550 mmHg	0-600 mmHg	-45 - 990 mmHg
Line Pressure Accuracy	line pressure 0-100 mmHg +/- 10 mmHg line pressure 101-500 mmHg +/- 10%	+/- 5 mmHg	+/- 2.5% or 3mmHg under all conditions	< 500 mmHg +/-10 mmHg 500 mmHg +/- 20 mmHg
External Pressure Accuracy	external pressure 0-100 mmHg +/- 5 mmHg external pressure 101-500 mm Hg +/- 5%	+/- 5 mmHg	+/- 2.5% or 3mmHg under all conditions	< 500 mmHg +/-10 mmHg 500 mmHg +/- 20 mmHg
Constant Pressure Mode Tolerance	pressure is maintained at +/-15% of target pressure; the flow required to maintain pressure varies no more than +/-25%	N/A	flow rate limits are adjustable by operator	N/A
Flow Rate	0-990 mL/min	10-600 mL/min	0 - 500 mL/min	0-9.8 L/min
Flow Accuracy	0-600 +/- 10% * 601-990 +/- 20%	+/-5%	+/-5%	0-2 L/min +/- .1 L/min 2-6 L/min +/- .2 L/min > 6 L/min +/- .3 L/min
Flow Ratios (Blood:Crystalloid)	0:1, 1:1, 2:1, ... 9:1 & 1:0, 1:1, 1:2, ... 1:9	0:1, 1:0, 1:1. 2:1, ... 16:1	0:1, 1:1, 2:1, ... 20:1 & 1:0, 1:1, 1:2, .. . 1:9	N/A
Temperature Range	0-50°C	0-40°C	0-39°C	0-49.9°C
Temperature Accuracy	+/- 1°C	+/- 1°C	+/- 1°C	+/- .2°C
Timer Range	0-99hr59min59sec	0-99.9 min	N/A	cardioplegia timer range is 0-1 hour; auxiliary timer range is 0 - 24 hours; clamp and pump timer range is 0-10 hours
Timer Accuracy	1 sec	.1 min	N/A	cardioplegia timer accuracy is +/- 1 min
Weight	11 kg	40 kg	22 kg	unknown
Display	LCD	LCD	LCD	LCD and CRT
Splash Proof	Yes	Yes	Yes	Yes
UL	Yes, CUL	Yes	Unknown	Yes
CSA	Yes, CUL	Yes	Unknown	Yes
CE**	Yes	Uknown	Unknown	Unknown

* Based on customer input this accuracy is sufficient for this application

** Application will be filed before international release.

COMPARISON DESIGN FEATURE

Feature	Medtronic CSS	Sorin BCC	Quest MPS	Sarns 9000
AC Power	Yes	Yes	Yes	Yes
AC Power Backup	Battery backup- fully functional 60 minutes of power-on time, including 15 minutes of pumping at typical operating parameters;	Yes Handcrank; device operates at a reduced functionality while on handcrank backup	No	Yes, battery backup and handcrank
No. of Blood-Crystalloid Pumps	2; 1 blood & 1 crystalloid pump	2; 1 blood & 1 crystalloid pump	2; 1 blood & 1 crystalloid pump	1; blood/crystalloid pump
Type of Pump	Roller	Roller	Piston	Roller
Flow Units	mL/min	mL/min	mL/min	L/min or RPM
Flow Direction	one way, disposable can be connected in only one way	both ways, depending on how disposables are connected	one way, disposable can be connected in only one way	both ways
Pulsatile Flow Control	No	No	No	Yes
Heater/Cooler	Separate and optional	Built-in	Built-in	Separate and optional
Temperature Sensor	Yes, 2 sensors	Yes, 2 sensors	Yes, 4 sensors	Yes, 3 sensors
Pressure Monitor	Yes, 1 internal sensor and 1 external delivery sensor	Yes, 2 sensors	Yes, 2 internal sensors and 1 external delivery sensor	Yes,
Pressure Zeroing	Yes	Yes	Yes	Yes
Pressure Units	mmHg or kPa	mmHg or kPa	mmHg	mmHg or kPa
User Adjustable Pressure Limits	Yes	Yes	Yes	Yes
Pressure Alarm	Yes	Yes	Yes	Yes
Pressure Alert	Yes	No	Yes	Yes
Constant Pressure Mode	Yes	No	Yes	No
Volume Monitor	Yes	Yes	Yes	Yes
Volume Units	mL	mL	mL	cc
User Adjustable Volume Limit	Yes	No	Yes	No
Volume Alert/Alarm	Yes	No	Yes	No
Arresting Agent Delivery	Yes, optional	No	Yes, optional	No
Separate Monitor Screen	No, built-in	Yes	No, built-in	Yes
Gross Air Monitor	Yes	No	Yes	Yes
Gross Air Alarm/Alert	Yes	N/A	Yes	Yes
Specified disposable sets	Yes	No	Yes	No
Alarm Type	Audio and visual	Audio and visual	Audio and visual	Audio and visual
Timers	Yes, 2	Yes, 2	No	Yes, 4: 1 cardioplegia timer 1 pump timer, 1 clamp timer, 1 auxiliary timer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1998

Mr. Thomas K. Johnson
Product Regulations Manager
Medtronic Cardiac Surgery
Medtronic Bio-Medicus, Inc.
9600 West 76th Street
Eden Prairie, MN 55344

Re: K973237
CSS™ Cardioplegia Safety System
Regulatory Class: II (Two)
Product Code: DWB
Dated: January 26, 1998
Received: January 27, 1998

Dear Mr. Johnson:

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 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,

Thomas J. Callahan

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K 973237

Device Name: *CSS™ Cardioplegia Safety System*

Indications For Use:

The Medtronic CSS™ Cardioplegia Safety System is intended for use as a cardioplegia delivery system which controls, monitors, and delivers oxygenated blood and/or asanguineous cardioplegia solution during cardiopulmonary bypass procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 973237

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)