

**APPENDIX I**

**510(k) Summary**

K070213

Medtronic Performer CPB System

MAR 21 2007

(As required by 21CFR 807.92)

**A. Submitter Information**

Submitter's Name: RAND S.r.l.  
Address: Via Sparato, 60  
41036 Medolla (MO) – ITALY  
Telephone Number: 763.391.9533 (for contact)  
Contact Person: Preeti Jain  
Date Submission Prepared: January 19, 2007

**B. Device Information**

Trade Name Performer Cardiopulmonary Bypass System  
Common Name Cardiopulmonary bypass heart-lung machine console  
Address of Manufacturing Facilities Manufacturing Site  
RAND S.r.l.  
Via Sparato, 60  
41036 Medolla (MO) – ITALY

Establishment Registration Number  
3003793891

FDA Classification Class II  
FDA Product DTQ  
Classification Code  
FDA Regulation Number 21 CFR 870.4220  
FDA Classification Panel Cardiovascular

**Predicate Devices:**

- Medtronic Performer CPB Advanced Extracorporeal Circulatory Support System (K052555)
- COBE Century Precision Blood Pump (K960974)
- Terumo Advanced Perfusion System 1 (K022947)
- RMR Automatic Tubing Clamp System (K961364)

**Device Description:**

The Performer CPB, is a next generation heart lung machine that integrates the primary functions and safety features needed to perform cardiopulmonary bypass and related circulatory support procedures, along with enhanced user conveniences, into a reduced sized instrument. The product is designed and manufactured by RAND S.r.l., Medolla, Italy for Medtronic and exclusively distributed by Medtronic Perfusion Systems.

This version of the device has been changed to add **conventional bypass capability** to the existing device which previously only supported the use of Medtronic Resting Heart Disposable Module. The conventional bypass refers to already marketed cardiopulmonary circuits that utilize a reservoir. Typical conventional circuits include oxygenators, reservoirs, centrifugal pump, filters, tubings, connectors etc. This updated version of the Performer only supports the Medtronic Bio-Medicus centrifugal Pump as the arterial pump.

The changes included in Version 1.5 of the device include the following:

- **Optional Level Detection capability for reservoirs:** Level detectors have been added to monitor changes in fluid or blood volume in the reservoirs. The system can be configured by the user to cause the Bio-Pump to either Stop or Coast in response to a level sensor being activated, preventing emptying the reservoir and transmitting air into the circuit. The user can also configure this safety link to not change the Bio-Pump function, but only produce visual and audible alarm cues. The level detection system is only utilized when operating with the reservoirs in the conventional cardiopulmonary bypass mode.
- **Optional Retrograde Detection and Occlusion capability:** An AutoClamp System has been added that utilizes a Remote Tube Clamp (RTC), placed on the arterial line which serves to prevent retrograde flow from the aorta into the venous reservoir if the Bio-Pump run mode changes. The AutoClamp System can be configured to automatically clamp the arterial line when the Bio-Pump speed changes, prevent retrograde flow and thereby prevent the potential to entrainment air around the aortic cannulation site. The AutoClamp System is only utilized when operating in the conventional cardiopulmonary bypass mode.

#### **Indications for Use:**

The Medtronic Performer CPB Advanced Extracorporeal Circulatory Support System is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in pumping blood through an extracorporeal perfusion circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours).

#### **C. Comparison of Required Technological Characteristics**

Medtronic Performer CPB System is a system comprised of standard components of an extracorporeal circuit for use during cardiopulmonary circulatory support. The

system has the same technological characteristics as a traditional circuit and the single components have the same technological characteristics as the predicate.

**D. Performance Data**

Performance data, such as, level sensing capabilities and AutoClamp retrograde detection capabilities have been provided in the 510(k) submission to show equivalence of the Medtronic Performer CPB System to RMR Automatic Tubing Clamp System, Terumo System 1 and Cobe system. In addition comprehensive testing has been completed on the machine including performance and Software Verification and Validation.

**E. Conclusion**

Medtronic Performer CPB System is substantially equivalent to the noted predicate devices based on the similarities of technological characteristics, indications for use and the results of performance comparative testing and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 21 2007

Rand S.R.L.  
c/o Ms. Preeti Jain  
Director, Regulatory/Clinical Affairs  
7611 Northland Drive  
Minneapolis, MN 55428

Re: K070213  
Performer CPB System  
Regulation Number: 21 CFR 870.4220  
Regulation Name: Cardiopulmonary bypass heart-lung machine  
Regulatory Class: Class II  
Product Code: DTQ  
Dated: January 19, 2007  
Received: January 22, 2007

Dear Ms. Jain:

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.

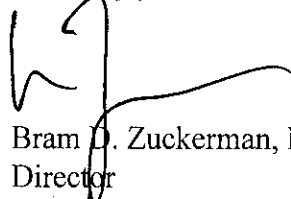
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Appendix II

### Indications for Use

510(k) Number (if known):

Device Name: Performer CPB

Indications For Use:

The Medtronic Performer CPB Advanced Extracorporeal Circulatory Support System is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

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Prescription Use   X   AND/OR Over-The-Counter Use           

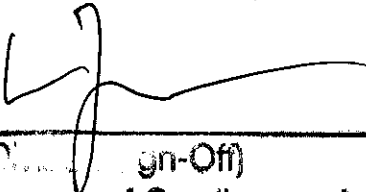
(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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(Print Name)                      (Sign-Off)

Director of Cardiovascular Devices

510(k) Number K070213