JUL 2 4 2013

510(k) Summary of Safety and Effectiveness

Date Prepared:	June 26, 2013
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Brooklyn Park, MN 55428 **Establishment Registration No. 2184009**
Contact Person:	Lisa Stone Principal Regulatory Affairs Specialist Medtronic, Inc. Cardiovascular 8200 Coral Sea Street NE, MVS 83 Mounds View, MN 55112 Phone: (763) 514-9866 Fax: (763) 367-8147 Email: lisa.j.stone@medtronic.com
Trade Name:	Bio-Console® 560 Extracorporeal Blood Pumping Console
Common Name:	Cardiopulmonary bypass pump speed control
Classification Name:	Control, Pump Speed, Cardiopulmonary Bypass
Classification:	Class II, 21 CFR 870.4380
Product Code:	DWA
Name of Predicate Device:	Bio-Console® 560 Extracorporeal Blood Pumping Console (K080824)

Device Description

The Bio-Console® 560 Extracorporeal Blood Pumping Console is an electromechanical, software-controlled device intended to allow the user to control a Bio-Pump® or Affinity® CP centrifugal blood pump that is used to return the blood to the body of a patient on cardiopulmonary bypass. As part of the blood pumping circuit, the patient's blood is typically pumped through an oxygenator and a filter on its return path to the patient. The Bio-Console 560 is a reusable non-sterile device.

Intended Use

The Medtronic centrifugal blood pumping system is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

Comparison to the Predicate Device

The Bio-Console 560 has the same intended use, hardware design and basic software as the previously cleared Bio-Console 560. The only change to the device is the incorporation of software enhancements to correct anomalies and to incorporate IEC 60601-1 (3rd Edition) compliant alarm and alert tones.

Summary of Performance Data

Software verification and validation testing confirms the function of the Bio-Console 560 and its software-controlled functional characteristics are substantially equivalent to the predicate device. All test data obtained satisfied the documented product and performance specification.

Conclusion

Based upon the technical information, intended use, and *in-vitro* verification and validation information for the Bio-Console 560 software enhancements addressed in this submission, the Bio-Console 560 has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

Medtronic, Inc.
Lisa Stone
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K131964
Trade/Device Name: Bio-Console® 560 Extracorporeal Blood Pumping Console
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: Class II
Product Code: DWA
Dated: June 26, 2013
Received: June 27, 2013

Dear Lisa Stone:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4 Statement of Indications for Use

510(k) Number: K131964

Bio-Console® 560 Extracorporeal Blood Pumping Console

Indications for use:

The Medtronic centrifugal blood pumping system is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)