K051303

JUN 10 2005

510(k) Summary

Date Prepared: May 18, 2005

Submitter:
Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:
Dawn M. Stenstrom
Principle Regulatory Affairs Specialist
Phone: (763) 391-9604
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Bio-Console® 560

Common Name: Cardiopulmonary bypass pump speed control

Classification: Class II

Predicate Devices: Bio-Console® 550
K924205

Bio-Console® 550M
K936091

Device Description:

The Bio-Console® 560 is a cardiopulmonary bypass pump speed controller. It is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

Indication 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).

Comparison to Predicate Devices

The Bio-Console® 550 and Bio-Console® 550M are cardiopulmonary bypass pump speed controllers with the same design characteristics. The modification to the current Bio-Console® 550 adds an additional pressure monitor and a remote touch screen user interface. Currently a remote user interface is used in the Bio-Console® 550M.

Summary of Performance Data

Functional, hardware and software testing was used to establish the performance characteristic of the modifications of this device from previously marketed devices.

Conclusion

Medtronic Perfusion Systems has demonstrated that the Bio-Console® 560 is substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2005

Medtronic Perfusion Systems
c/o Ms. Dawn M. Stenstrom
Principle Regulatory Affairs Specialist
7611 Northland Boulevard
Brooklyn Park, MN 55428

Re: K051303
Bio-Console® 560
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: Class II
Product Code: DWA
Dated: May 18, 2005
Received: May 19, 2005

Dear Ms. Stenstrom:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

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

Enclosure

Indications for Use

510(k) Number (if known): K051303

Device Name:

Bio-Console® 560

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___ AND/OR Over-The Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochnes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051303