K973011

SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 25 1998

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

August 12, 1997

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

Thomas K. Johnsen
Product Regulations Manager

DEVICE NAME

BPX-80 Bio-Pump®

COMMON NAME

Centrifugal Blood Pump

CLASSIFICATION NAME

Non-roller type cardiopulmonary bypass blood pump (21 CFR - 870.4360)

PREDICATE DEVICE OR LEGALLY MARKETED DEVICE

Medtronic Bio-Medicus, Inc. - BP-80 Bio-Pump® (K852698)

Medtronic Cardiopulmonary - CBBP-80 Bio-Pump® (K852698, K891687 and K896978)

DEVICE DESCRIPTION

The BPX-80 Bio-Pump® centrifugal blood pump is a single use, disposable, non-pyrogenic device designed to move blood through the extracorporeal circuit by centrifugal force created by smooth rotating cones. Venous blood gravity drains into the inlet port of the Bio-Pump®. The smooth cones rotate in the polycarbonate housing. As the cones rotate, energy in the form of pressure and velocity is transferred from the cones to the blood. The blood is gently accelerated toward the outlet of the pump. The Bio-Pump® moves the blood through the circuit at a desired pressure and flow rate by increasing or decreasing the speed of the rotating cones. This is accomplished by adjusting the Bio-Console's RPMs (revolutions per minute). Arterial blood is returned to the patient from the extracorporeal circuit.

The BPX-80 Bio-Pump® consists of a housing and backplate, three smooth surface cones, a magnet, and a bearing/shaft assembly. The plastic components of the BPX-80 Bio-Pump® are molded from polycarbonate. The joints are bonded with an ultraviolet light cured adhesive. The inlet port (3/8") is located at the top center of the Bio-Pump®, and the outlet port (3/8") is located tangentially on the outer diameter. Notches on the backplate allow the BPX-80 Bio-Pump® to be securely locked onto the pump receptacle of the Bio-Console®. The BPX-80 Bio-Pump® is designed to be used only with Medtronic® Bio-Medicus® Bio-Consoles®.

The BPX-80 Bio-Pump® centrifugal blood pump can be sterilized by either gamma radiation or ethylene oxide (EtO) gas. The Bio-Pump® is also available with a heparin bonded (non-leaching) Carmeda® Bioactive Surface.

INTENDED USE

The Medtronic Bio-Medicus Bio-Pump® centrifugal blood pump is indicated for use only with the Medtronic Bio-Medicus Bio-Console® to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are identical ~~to the BP-80 Bio-Pump®~~, with the exception of the following modifications; material change (acrylic to polycarbonate), dimensional change (internal dimensions of the port), and UV adhesive in place of solvent bond. The packaging material, sterilization methods/cycles, optional heparin bonding (Carmeda® Coating), drive magnet, bearing assembly, internal seal and component specifications are identical to the currently marketed BP-80 Bio-Pump®.

SUMMARY OF PERFORMANCE DATA

In-vitro Bench Testing:

In-vitro bench testing demonstrated that when compared to the predicate devices (BP-80 Bio-Pump® and CBBP-80 Bio-Pump®), the BPX-80 Bio-Pump® and CBBPX-80 Bio-Pump® do not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed centrifugal blood pumps. The in-vitro bench testing included analysis of:

- Hydraulic Performance and Priming Volume Tests
- Chemical Resistance Tests
- Environmental Tests
- Carmeda® Coating Tests
- Complement Activation
- HIMA - Hemolysis Testing

Biocompatibility:

Biocompatibility testing of the BPX-80 Bio-Pump® was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance - International Standard ISO 10993-1, and in accordance with United States Pharmacopoeia - XXIII.

Based on the results of the biocompatibility testing performed, the BPX-80 Bio-Pump® was determined to be biocompatible and nontoxic and, therefore, safe for its intended use. Biocompatibility on the CBBPX-80 Bio-Pump® has been substantiated by over 8 years of the Carmeda® Bioactive Surface being applied to Cardiopulmonary bypass products, many of which have polycarbonate housing materials.

Sterilization:

Sterilization of the BPX-80 Bio-Pump® has been validated to assure a sterility assurance level (SAL) of 10^{-6}.

Gamma radiated Bio-Pumps® are sterilized in accordance with ANSI/AAMI/ISO 11137 - Method 1, Sterilization of Health Care Product Requirements for Validation and Routine Control - Radiation Sterilization.

EtO sterilized Bio-Pumps® are sterilized in accordance with 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 are used for routine product release to assure EtO sterilized Bio-Pumps® meet the limits for residual concentrations of ethylene oxide (<25ppm), ethylene chlorohydrin (<25ppm), and ethylene glycol (<250ppm) as published in ANSI Standard Number ANSI/AAMI/ISO 10993-7 (Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals).

Pyrogens:

Routine Pyrogen Testing is 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 Guideline 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

BPX-80 Bio-Pump® is substantially equivalent to the BP-80 Bio-Pump®. Performance, functional, and biocompatibility testing demonstrated that there are no new safety and effectiveness questions raised by the modifications made to the currently marketed BP-80 Bio-Pump®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

FEB 25 1998

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

Re: K973011
BPX-80 Bio-Pump Centrifugal Blood Pump
Regulatory Class: III
Product Code: KFM
Dated: November 25, 1997
Received: November 28, 1997

Dear Mr. Johnsen:

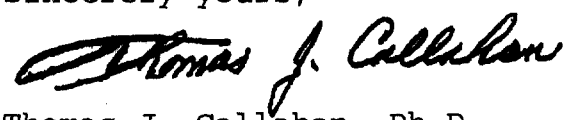
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have 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/dsma/dsmamain.html."

Sincerely yours,



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

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number: K973011

Device Name: **BPX-80 Bio-Pump® Centrifugal Blood Pump**

Indications for use:

The Medtronic Bio-Medicus Bio-Pump centrifugal blood pump is indicated for use only with the Medtronic Bio-Medicus Bio-Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K973011

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

(Division Sign-Off) Number

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

(Optional Format 1-2-96)