

NOV -1 2000

K991783

510(k) Summary
K991783

 **Cardiac Assist Technologies, Inc.**

510(k) Summary

February 25, 2000

Company Name and Address

Sponsor/Manufacturer
Cardiac Assist Technologies, Inc.
240 Alpha Drive
Pittsburgh, PA 15238
Contact Individual: Richard G. Confer
Telephone: (412) 963-7770
Fax: (412) 963-0800

Device Name

Proprietary Name: AB-180 XC System
Common/Usual Name: Centrifugal Blood Pump
Classification Name: Pump, Blood, Cardiopulmonary Bypass, Non-roller type

Establishment Registration Number

Manufacturing Site
Registration Number 2531527
Owner Operator Number 9028561
Cardiac Assist Technologies, Inc.
240 Alpha Drive
Pittsburgh, PA 15238

Device Classification

Non-roller type blood pumps have been classified as Class III devices by the

Cardiovascular Devices Panel
Product Code 74KFM

Note: A petition for reclassification of this type of device from Class III to Class II has been approved by the panel, but the final rule has not been promulgated yet.

Predicate Device or Legally Marketed Device

Medtronic BP-80 Bio-Pump®, K973011, K852698
Hemadyne Minnimed™ Model 1861 Extracorporeal Blood Pump, K780953

Device Description

The AB-180 XC Blood Pump provides extracorporeal circulatory system support with the unique ability to locally deliver an anticoagulant through the infusate system. The Pump is electrically driven and can only be used with the AB-180 XD Blood Pump Controller. The AB-180 XD Blood Pump Controller provides pump monitoring, manual pump speed variability and a constant flow of infusate to the Pump.

The AB-180 XC Blood Pump consists of an upper and lower housing. The upper housing encloses the blood contact area of the Pump and holds the impeller, which propels the blood through the Pump. This chamber has a low priming volume. Two tubes connect to this chamber allowing easy connection to extracorporeal circulatory support circuits. The lower housing contains the main rotating component (the rotor) and has an inlet port for the infusion fluid. This infusate acts as a fluid bearing and a local anticoagulation delivery system.

Statement of Intended Use

The AB-180 XC System consists of the AB-180 XC Blood Pump, a single use, disposable device; the AB-180 XD Blood Pump Controller; a reusable control system for the AB-180 XC Blood Pump; and disposable accessory items used in conjunction with the AB-180 XC Blood Pump. The extracorporeal circuit is not supplied with the AB-180 XC System.

The AB-180 XC Blood Pump is a single use, disposable centrifugal blood pump designed to circulate blood through an extracorporeal circuit. The AB-180 XC Blood Pump is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant, etc.).

Technological Characteristics

The technological characteristics of the AB-180 XC Blood Pump are identical to the Hemadyne Minnimed™ Model 1861 Extracorporeal Blood Pump with the exception of the following modifications:

- The impeller material has been changed from pyrolytic carbon to polysulfone
- The AB-180 XC Blood Pump contains an integral stator winding for the DC brushless motor, whereas the Minnimed 1861 was magnetically coupled to the drive unit.
- The Minnimed 1861 was reusable whereas the AB-180 XC Blood Pump is for single patient use and is disposable.

Summary of Performance Data

In-vitro Bench Testing:

The AB-180 XC Blood Pump was compared to the predicate device, the Medtronic BP-80 Bio-Pump®, via a battery of in-vitro bench tests. These tests demonstrated that the AB-180 XC Blood Pump is substantially equivalent to commercially distributed centrifugal blood pumps. The in-vitro bench testing included analysis of the following:

- Hydraulic Performance Tests
- Safety and Environmental Tests to IEC 60601-1, IEC 60601-1-2 and IEC 68
- Hemolysis Testing

Biocompatibility:

Biocompatibility testing of the AB-180 XC Blood Pump was performed in accordance with the FDA Blue Book Memorandum – G95-1 and appropriate sections of Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1.

Biocompatibility testing in accordance with these standards demonstrated that the AB-180 XC Blood Pump is biocompatible and non-toxic and, thus, safe for its intended use. The AB-180 XC Blood Pump is lubricated by the infusion of a sterile biocompatible solution; and, thus, there are no biocompatibility issues associated with the infusate.

Sterilization:

Sterilization of the AB-180 XC Blood Pump has been validated to assure a sterility assurance level (SAL) of 10^{-6} .

EtO dissipation curves are used to assure that the EtO sterilized AB-180 XC Blood Pump meets the limits for residual concentrations of ethylene oxide and ethylene chlorohydrin as published in ANSI Standard Number ANSI/AAMI/ISO 10993-7:1995 (Biological Evaluation of Medical Devices – Part 7: Ehtylene Oxide Sterilization Residuals).

Pyrogens:

The Limulus Amebocyte Lysate (LAL) method is used for pyrogen testing. LAL testing is performed on the AB-180 XC Pump and release criteria is in accordance to the December 1987 Guideline issued by the FDA, Office of Compliance (Guideline of 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

The Cardiac Assist Technologies, Inc. AB-180 XC System is substantially equivalent to the Hemadyne Minnimed Model 1861 Blood Pump and control system, K780953, and the Bio-Medicus BP-80 Bio-Pump and Bio-Console, K852698 and K973011. The intended use, indications for use, and technological characteristics, safety information and performance data support the substantial equivalence of the AB-180 XC System.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardiac Assist Technologies, Inc
C/O Joe Schwoebel, RAC
Vice President of Regulatory Affairs
240 Alpha Drive
Pittsburgh, PA. 15238

Re: K991783
AB180 XC System, Model AB-180XC
Regulatory Class: III (three)
Product Code: KFM
Dated: June 22, 2000
Received: June 23, 2000

Dear Mr. Schwoebel:

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 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). 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.

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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" (21CFR 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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Cardiac Assist Technologies, Inc.

Indications For Use Statement

510(k) number: K991783

Device Name: AB-180 XC System

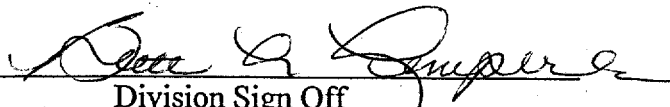
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Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign Off

Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K991783

Prescription Use: (Per 21 CFR 801.109)

or Over the Counter Use

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