

3/24/99

K983272



510(k) SUMMARY

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COMPANY NAME AND CONTACT PERSON

September 16, 1998

International Biophysics Corporation (IBC)
4020 South Industrial Drive
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Tel. (512) 326-3244
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H. David Shockley, Jr.
President

DEVICE NAME

IBC FloPump
Catalog Number 6000

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)

INTENDED USE

The IBC FloPump 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).

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The IBC FloPump is a single use, disposable centrifugal blood pump that is intended for use during open-heart surgery. The device is designed for and limited to use with the BioMedicus BioPump Console and must be used in accordance with the operating parameters of that device. Directions for Use are included with the IBC FloPump and are the same as the BioMedicus Bio-Pump. The fully assembled IBC FloPump head is a geometric duplicate of the BioMedicus BioPump.

The IBC FloPump device is composed of a conical rotor mounted on two ball bearings on the shaft within a generally conical shaped housing. The rotor contains a sealed Strontium Ferrite ring shaped magnet. The magnet is magnetized to 1500 gauss through its thickness every 60 degrees in an alternating north-south and south-north configuration. This enables the rotor to magnetically couple to a similarly configured magnet in the BioMedicus BioPump Console such that the rotor in the IBC FloPump rotates with the magnet in the console. The rotor has two generally conical shaped components attached in close proximity to the magnet housing such that blood contained in the housing forms two generally conical flow paths. The inlet to the housing is in the top center of the housing and the outlet is located on the lower side of the housing tangent to the outer diameter of the rotor. This geometry is identical to the geometry of the predicate device, the BP80 BioMedicus BioPump Pump Head.

In use, the rotor subassembly is spun within the housing subassembly by means of the magnetic coupling to the BioMedicus BioPump Console. The blood enters the inlet by gravity and fills the housing such that the two conical flow paths are fully primed. Due to the high surface area to volume ratio of the flow paths, the cohesive force between the blood and rotor members causes the blood to spin. The blood is thereby gently accelerated to about the same angular velocity as the rotor. The resultant centrifugal force causes the blood to move in a direction tangent to the outer diameter of the rotor. The outlet from the housing is centered on the lower edge of the conical flow channels of the rotor and tangent to the outside diameter of the rotor. This dynamic energy provides the pumping power without the use of rotor vanes. The dynamics of the IBC FloPump are identical to the dynamics of the BioMedicus BioPump.

There are two technological characteristic differences between the IBC FloPump and the predicate device, the original BioMedicus BioPump. The first of these differences is the choice of polymer for molding the plastic components. The IBC FloPump plastic components are made of clear polycarbonate and the BioMedicus BioPump plastic components are made of acrylic. The polycarbonate has greater clarity and a higher impact resistance. Upon review of the predicate device, the warning to avoid contact with isopropyl alcohol was noted. The use of polycarbonate eliminated that problem. Also, polycarbonate is widely used in a large number of cardiovascular medical devices, and specifically two other brands of centrifugal blood pumps that are currently marketed. Secondly, the main shaft of the IBC FloPump is insert molded into the base of the pump assembly and the BioMedicus BioPump has a main shaft, that is assembled using various rubber seals and formed metal components held together with threads and a nut. The insert-molded shaft eliminates leakage by eliminating the potential leak path, assembly tolerances and stress points from the load-bearing portion of the assembly. This method of insert molding the shaft base has been used on another marketed centrifugal pump brand for years. These two minor technological differences do not raise any new questions concerning the safety and effectiveness of the device.

The magnet for coupling the pump head to the pump console in both products is made of Strontium Ferrite and magnetized to 1500 Gauss. The rotor bearings and bearing assembly of both products are the same part number from the same bearing manufacturer. Both products are identical in these respects.

The IBC FloPump was in-vitro bench tested for performance evaluation. The IBC FloPump was subjected to a series of flow tests in a side by side comparison with the BioMedicus BioPump. The RPM required to generate specific flow rate and output pressure was measured at one liter intervals from one to seven liters per minute. The data generated was insignificantly different between each IBC FloPump tested, and insignificantly different between the IBC data and the BioMedicus data. The IBC FloPump was also compared to the BioMedicus BioPump for hemolysis. While the IBC data indicates that the IBC FloPump had lower hemolysis than the BioMedicus BioPump, it is the opinion of IBC that the blood trauma is too low in either system to attribute significance to the differences seen. This testing demonstrates the IBC FloPump does not raise any new safety and effectiveness questions, and it is substantially equivalent to the predicate device, BioMedicus Bio-Pump.

The IBC FloPump is manufactured at IBC in a Class 100,000 clean room. The Bioburden prior to sterilization is extremely low, meets IBC criteria and comparable to other products manufactured by IBC. The IBC FloPump is labeled non-pyrogenic (less than 0.5 EU/ml) and this is tested and validated by the LAL method. The device will be packaged and sterilized for single use. The IBC FloPump has passed our sterilization validation test, meets the IBC SAL standard, meets the sterilization residue standards in accordance with ISO 10993-7, and the packaging has been validated to maintain sterility for 2 years using accepted accelerated aging methods and microbial challenged. Additionally, the IBC FloPump will be packaged in bulk form and non-sterile for the Custom Perfusion Tube Pack market. The materials used to manufacture the IBC FloPump are biocompatible and non-toxic and, therefore, safe for its intended use in accordance with ISO 10993-1 standard. In addition, these same materials have been used in other IBC products in the same manufacturing process for years.

An end user substituting an IBC FloPump for BioMedicus BioPump in his or her perfusion circuit will be unable to distinguish between the two pumps functionally. Performance, functional, and biocompatibility testing demonstrated that there are no new safety and effectiveness questions raised by the IBC FloPump. The IBC FloPump is substantially equivalent to the Medtronic BioMedicus Bio-Pump, BP-80.



MAR 24 1999

Food and Drug Administration
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Rockville MD 20850

Mr. H. David Shockley, Jr.
President
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Re: K983272
IBC FloPump, Model 6000
Regulatory Class: III (Three)
Product Code: 74 KFM
Dated: January 11 1999
Received: January 14, 1999

Dear Mr. Shockley:

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,



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

Enclosure

