

MAY 14 1998

K971421

Bard Vascular Systems Division  
C.R. Bard, Inc.  
25 Computer Drive  
Haverhill, MA 01832  
508-373-1000



## 510(k) SUMMARY FOR THE BARD<sup>®</sup> ISOFLOW<sup>®</sup> BLOOD PUMP

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92.

### I. Submitter Information:

Name: Bard Vascular Systems Division, C.R. Bard Inc.  
Address: 25 Computer Drive, Haverhill, MA 01832  
Contact Person: Sandra L. Perreand  
Date Summary Prepared: April 14, 1997

### II. Device Name:

Proprietary Name: Bard<sup>®</sup> Isoflow<sup>®</sup> Blood Pump  
Common or Usual Name: Blood Pump  
Classification Name: Cardiopulmonary Bypass Pump Speed Control

### III. Predicate Device(s):

- 1) Bard<sup>®</sup> Lifestream<sup>®</sup> Blood Pump

### IV. Device Description:

The Blood Pump Console is made up of the console, one power cord, and an Operator's Guide. The console is a microprocessor based system which drives and controls the speed of the disposable centrifugal blood pump in the extracorporeal circuit. Each console operates off of single phase AC power and is capable of a flow rate of up to 8 LPM against a maximum pressure head of 600 mmHG. In addition each console comes with an internal battery which is capable of running the pump for a minimum of 30 minutes when fully charged in the event of a loss of AC power.

### V. Indications for Use:

The IsoFlow<sup>®</sup> Blood Pump System is indicated as a component of an extracorporeal circuit to initiate and maintain blood flow for up to six hours.

## **VI. Technological Characteristics:**

The Isoflow<sup>®</sup> Blood Pump Console (QB2521) is an integral part of our Blood Pump System (QB2520). Each IsoFlow<sup>®</sup> Blood Pump System is made up of four components. They are as follows:

- A.** The **Blood Pump Console** (QB2521) is made up of the console, one power cord, and an Operator's Guide. The console is a microprocessor based system which drives and controls the speed of the disposable centrifugal blood pump in the extracorporeal circuit. Each console operates off of single phase AC power and is capable of a flow rate of up to 8 LPM against a maximum pressure head of 600 mmHG. In addition each console comes with an internal battery which is capable of running the pump for a minimum of 30 minutes when fully charged in the event of a loss of AC power.
- B)** The **Remote Motor Drive** (QB2522) is positionable on an IV pole/mast or on the console using an optional utility post. The drive holds the disposable pump head and drives the blood flow through magnetic coupling between the pump head and the motor drive. The remote motor drive includes the motor drive, an Allen wrench, one motor drive holder assembly, and an IFU.
- C)** The **Flow Sensor** (QB2523) is a reusable, non-patient contacting ultrasonic flow sensor which can detect flows from 0-10 LPM and can detect retrograde flow of  $\geq 40$  cc/min. This sensor is compatible with 3/8" ID by 3/32" wall tubing. Each flow sensor includes the flow sensor, one tube of petroleum jelly, a plastic storage case, and an IFU.
- D)** The **Hand Crank** (QB2524) provides a manual means of driving the pump head in the event that both AC and battery power are unavailable to the pump. This hand crank provides sufficient power to deliver 7 LPM of blood flow against a 600 mmHg pressure head. Each hand crank includes one hand crank body, one hand crank handle, one hand crank holder, one serial number label, three screws, two Allen wrenches, and an IFU.

## **VII. Performance testing**

To verify that the changes did not adversely impact the performance of the console the affected boards were validated and the system validation was repeated. In addition EMC testing was conducted per EN60601-1-2 to verify the device's resistance to EMC.



MAY 14 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sandra L. Perreand  
Regulatory Affairs Manger  
Bard Cardiology-Cardiopulmonary  
Cardiac Assist Products  
Bard Vascular Systems Division  
C.R. Bard, Inc.  
25 Computer Drive  
Haverhill, MA 01832

Re: K971421  
Bard® IsoFlow® Centrifugal Blood Pump System  
Regulatory Class: II (Two)  
Product Code: DWA  
Dated: February 12, 1998  
Received: February 13, 1998

Dear Ms. Perreand:

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" (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

510(k) Number (if known): K971421

Device Name: Bard IsoFlow Blood Pump System

Indications For Use:

The IsoFlow Blood Pump System is indicated as a component of an extracorporeal circuit to initiate and maintain blood flow for up to six hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K971421

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_