K981284

SAFETY AND EFFECTIVENESS

**510(k) Summary**

Once a substantial equivalence determination is made, a 510(k) summary providing information on the safety and effectiveness of the Better-Bladder™ will be provided upon the request of any person. The 510(k) summary is included in Attachment 5.

**Functional Testing**

With respect to this notification, the Better-Bladder™ was functionally evaluated in a series of bench tests. The test protocols, experimental data, and analyses are provided as Attachment 6. These tests and the data obtained demonstrate that the pressure measured noninvasively with the BB is equivalent to that measured invasively, and that the BB shows comparable or superior performance to the predicate devices.

**General Safety**

See K964337.

**Sterilization, Sterilant Residuals, Pyrogenicity**

See K964337.

**Biocompatibility**

See K964337.

**Quality Assurance**

See K964337.

## SUBSTANTIAL EQUIVALENCE

### Predicate Devices

The Better-Bladder™ is substantially equivalent to the following devices:

| Company Name | Product Name (Model) |
|---|---|
| Quest Medical (formerly Delta Medical Industries) | Pressure Monitoring Separator Chamber (PMS-2) |
| SciMed Surgical (now AVECOR Cardiovascular) | R30 Assist Reservoir |

These devices are currently available cardiovascular and/or dialysis devices that have been determined to be substantially equivalent to devices in commercial distribution prior to May 28, 1976.

### Same Intended Use

### The Better-Bladder™

The Better-Bladder™ (BB) has two intended uses:

1. To isolate pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short or long term procedures.
2. As an inline blood reservoir, such as the bladders used to sense decreasing pump inlet pressure. The pressure signal can be used to control pump speed during short or long term procedures.

### Predicate Devices

The Quest Pressure Monitoring Separator Chamber is intended to help in the monitoring of arterial pressure by providing an air-liquid phase separator (same as BB use 1).

The R30 Assist Reservoir is intended to hold a reserve supply of blood in the perfusion circuit and is designed to sense venous return pressure during ECMO procedures (same as BB use 2). It incorporates two vent tubes at the top for air aspiration or drug infusion.

### Technological Characteristics

The technological characteristics of the BB do not affect its safety and effectiveness. The equivalency of the blood contacting portion of the BB with respect to a) material, b) design, c) general manufacturing methods, and d) use in an extracorporeal circuit is discussed below.

**a) Material.** The blood of the patient is only exposed to the inner surface of the tubing forming the BB. The blood path of the BB consists of a medical grade tubing extruded from a polyvinyl chloride formulation that has passed biiocompatibility tests in accordance with ISO 10993 Part-1 Biological Evaluation of Medical Devices.

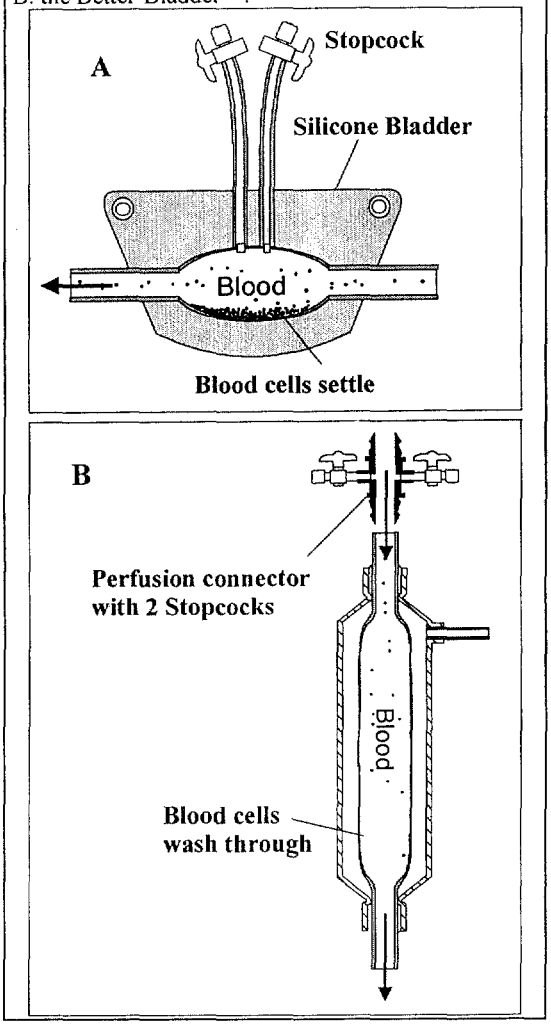
**b) Design.** The BB consists of a unitary length of tubing, a section of which has been processed to form an enlarged diameter with a thinner wall. The enlarged section is very responsive to pressure differences across its thin wall. Because the entire device is made from a single length of smooth perfusion tubing, there are no connections between the thinner and thicker wall tubing portions. This unique design eliminates both physical and material (chemical) discontinuities. The thin walled section in its housing can withstand over 1500 mmHg (three times the maximum pressure expected under worst-case clinical conditions). The BB does not incorporate vent tubes for air aspiration or drug infusion. These can be added by placing a perfusion connector with a dual Luer fitting (e.g. Avecor Model # DL1414) at the inlet to the BB, see Fig. 7b.

**c) General Manufacturing.** The blood path of the BB is an extruded tube, part of which is formed in a secondary operation.

The Housing of the BB, made of PETG, does not contact the patient and therefore its physical characteristics, rather then its blood compatibility, are important. Each BB is individually tested to an internal pressure as well as a Housing pressure of 900 mmHg, which is 1.8 times the maximum clinically expected pressure and also significantly higher than the maximum operating pressures recommended for many devices in the extracorporeal circuit. Tests have also been conducted where a pressure of 1500 mmHg was applied internally to the BB without any failure.

The thin walled section of the unitary tubing forming the BB is sealed within the Housing by forming a bond between the outside of the unitary tubing and the inside of the Housing. The bonding is external to the blood path and therefore does not pose any blood compatibility concerns.

Fig. 7. Flow conditions with A. Predicate Devices B. the Better-Bladder™.




**d) Use in an extracorporeal circuit.** Most extracorporeal circuits monitor pump inlet and/or pump outlet pressures, but typically with "dead-ended" pressure lines. Since the BB is a flow-through device, stagnation is eliminated and the likelihood of thrombosis is decreased. The predicate bladders must be positioned horizontally, and are thereby susceptible to stasis and blood cell accumulation at the bottom of the device (see Fig. 7A), which can contribute to thrombus formation.

## HOW THE BETTER-BLADDER™ ENHANCES SAFETY AND EFFECTIVENESS

1. The bubble in the tube is formed such that its internal surface is continuous and fissureless, thereby eliminating chemical or physical discontinuities, factors that can increase thrombus formation.
2. In terms of bladders, the predicate bladders must be positioned horizontally, and are thereby susceptible to stasis and blood cell accumulation at the bottom of the device, both of which can contribute to thrombus formation. The BB can be placed vertically, thus providing gravitational washout that significantly reduces stasis or accumulation of red cells (see Fig. 7).
3. The BB can provide adjustable compliance that reduces pressure oscillations due to pumping action of the roller pump.
4. The predicate bladder must be placed on the floor to achieve appropriate gravitational flow. The BB, however, can be placed much closer to the patient with the loss of "gravity" drainage compensated by applying slight negative pressure to the housing. This allows for shorter venous tubing which reduces the prime volume, the foreign surface exposed to blood as well as the exposure time of the blood to the surface. The shorter circuit and smaller surface area also reduces heat loss of the blood in the extracorporeal circuit.
5. In terms of pressure isolators, the BB is a flow-through device, reducing the chance of clotting. The predicate devices can pose greater risk of clotting because there is NO flow in the pressure line connecting the blood path to the isolator.
6. If the BB is used to obtain a pressure signal to control the pump, the pressure at which the pump would turn off is easily adjustable via the pressure monitor. The predicate bladder relies on a mechanical switch and is not adjustable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1998

Mr. Yehuda Tamari
President
Circulatory Technology, Inc.
21 Singworth Street
Oyster Bay, NY 11771

Re: K981284
"Better-Bladder™"
Regulatory Class: II
Product Code: DTN
Dated: May 13, 1998
Received: May 14, 1998

Dear Mr. Tamari:

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.

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

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

Enclosure

**Attachment 10**
**Better-Bladder™**
**Indications for Use**

510(k) Number K981284
Device Name: Better-Bladder ™

Indications for Use: The Better-Bladder™ is a device that isolates pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short and long term procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and long term procedures.

K981284

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