

FEB 18 2000

K992657

EXECUTIVE SUMMARY

The IBC VRV Valve is a single use, disposable, vacuum and pressure relief, check valve that is intended for use during open-heart surgery for left ventricular venting. It is sometimes commonly referred to as a suction control valve for left ventricular venting. The device is designed for use in a suction line and must be used in accordance with the operating parameters of that blood recovery line. The fully assembled IBC VRV Valve is geometrically similar and clinically the same to the Omni Model RLV-2100"B" VRV valve, which is the predicate device for purposes of this 510(k) submission. The operating principles of the two devices are identical.

The differences between the IBC VRV and the predicate device are found in the material selection and specific dimensions of the component parts neither of which effects safety or effectiveness of the product. The first of these differences is the choice of polymer for molding the plastic components. The main flow through body of the IBC VRV is made of polycarbonate and the Omni RLV-2100"B" is made of ABS. The polycarbonate is clear, has higher impact resistance, greater tensile and compression strength and superior chemical. Upon review of the predicate device, we found the inability to see the interior of the device made it difficult for the user to identify the vacuum relief point. The use of polycarbonate eliminated that problem. Secondly, the straight duck bill check valve in the predicate device represents a substantial resistance to flow which contributes significantly to hemolysis. The unique curved design of the duckbill check valve in the IBC VRV substantially reduces flow resistance and hemolysis.

The IBC VRV (sterile, 6 month aged, environmentally conditioned) was subjected to a series of dynamic tests in a side by side comparison with the Omni RLV-2100"B". The vacuum relief rate for both products was measured in a dynamic circuit flowing blood at 2 liters per minute. The pressure drop of the check valves for both products were measured also at 2 L.P.M. flow with blood. Hemolysis was measured in a simulated clinical circuit at 2 L.P.M. for 6 hours using fresh bovine blood at 45% hematocrit. The reverse-flow and over-pressure vent was tested with air for both products to simulate reverse flow pump failure mode. Comparison of the IBC VRV to the Omni RLV-2100"B" demonstrates that the two products are substantially equivalent when used clinically.

The IBC VRV is manufactured in a Class 100,000 clean room. The Bioburden prior to sterilization is extremely low and comparable to other 510(k) listed products manufactured by IBC. The device will be packaged and sterilized for single use using the same packaging and sterilization as other IBC products. Additionally, the IBC VRV will be packaged in bulk form and non-sterile for the Custom Perfusion Pack market. The materials used to manufacture the IBC VRV are non-toxic using the tripartite biocompatible ISO standards and the FDA modified matrix of 1995.

A perfusionist substituting an IBC VRV for an Omni RLV-2100"B" in his or her perfusion circuit will be unable to distinguish between the two valves functionally.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. H. David Shockley, Jr.
President
International Biophysics Corporation
4020 South Industrial Dr.
Suite 160
Austin, Tx 78744

Re: K992657/S1
IBC VRV, Model 1350
Regulatory Class: II
Product Code: DWD
Dated: November 19, 1999
Received: November 22, 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 (Pre-market 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

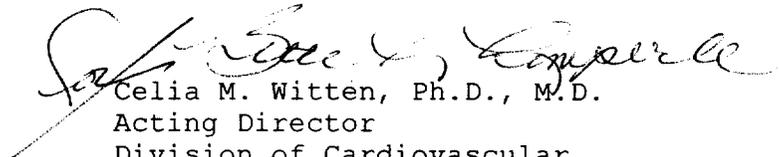
This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding

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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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Celia M. Witten", is written over the typed name and title.

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

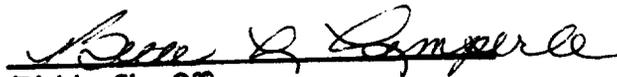
510(k) Number: K992657

Device Name: IBC VRV

Indications for use:

The IBC VRV is indicated for use as an intracardiac suction control valve for left ventricular venting during cardiopulmonary bypass surgery (up to six hours).

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



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

510(k) Number K992657

Prescription Use _____
(Per 21 CFR 801.109)

or Over-The-Counter-Use _____