JAN 14 2000

K992785

EXECUTIVE SUMMARY

The IBC FloGard is a single-use, disposable, check valve intended for use for the prevention of retrograde flow in the arterial line when used with centrifugal pumps during open-heart surgery. The device is designed for use in the main arterial line when centrifugal pumps are used. The fully assembled IBC FloGard Valve is geometrically similar to the Quest RetroGuard 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, specific dimensions of the component parts and the type of check valve used. 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 Quest RetroGuard is made of clear ABS. The polycarbonate is clearer, has higher impact resistance, greater tensile and compression strength and superior chemical resistance. Secondly, the straight duck bill check valve in the predicate device, Quest RetroGuard, required an oversized body to accommodate clinical flow rates without a substantial resistance to flow. The bi-leaflet design of the check valve in the IBC FloGard valve substantially reduces the size of the flow through housing without increasing resistance to flow. This geometry substantially lowered prime volume and hemolysis.

The IBC FloGard (sterile, 6 month aged, environmentally conditioned) was subjected to a series of dynamic tests in a side by side comparison with the Quest RetroGuard. The pressure drop of the check valves for both products were measured at 4 L.P.M. flow (average clinical flow rate) with blood at 45% hematocrit. Hemolysis was measured in a simulated clinical circuit at 7 L.P.M. for 6 hours using fresh bovine blood at 45% hematocrit. The reverse-flow was measured at 100 mm Hg back-pressure for both products to simulate reverse flow in a pump failure mode. Pressure required to close both valves in the reverse direction was also measured. Comparison of the IBC FloGard to the Quest RetroGuard demonstrates that the two products are substantially equivalent when used clinically.

The IBC FloGard valve 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 510(k) listed products. Additionally, the IBC FloGard valve will be packaged in bulk form and non-sterile for the Custom Perfusion Pack market. The materials used to manufacture the IBC FloGard are non-toxic using the tripartite biocompatible ISO standards and the FDA modified matrix of 1995.

A perfusionist substituting an IBC FloGard valve for a Quest RetroGuard in his or her perfusion circuit will be unable to distinguish between the two valves functionally.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2000

Mr. H. David Shockley, Jr.
President
International Biophysics Corp.
4020 South Industrial Drive
Suite 160
Austin, TX 78744

Re: K992785
IBC FloGuard, Model 6050
Regulatory Class: II
Product Code: MJJ
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 (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 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

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,

for 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: k992785

Device Name: IBC FloGard

Indications for use:

The IBC FloGard is indicated for use for the prevention of retrograde flow when used with centrifugal pumps during cardiopulmonary bypass surgery (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 Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use X or Over-The-Counter-Use
(Per 21 CFR 801.109)