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K992964

510(k) SUMMARY

The IBC Vent Valve is a single use, disposable, vacuum relief valve that is intended for use to maintain a low level of vacuum in reservoirs. The valve is closed until the vacuum reaches a pre-determined value in the reservoir and operates best when the pump runs at a very slow rate. The fully assembled IBC Vent Valve is basically identical to the American Omni Vent Valve, which is the predicate device for purposes of this 510(k) submission. The operating principles, performance and indications for use of the two devices are the same.

The IBC Vent Valve is manufactured in a Class 100,000 clean room. The device will be packaged and sterilized for single use. Additionally, the IBC Vent Valve will be packaged in bulk form and non-sterile for the Custom Perfusion Pack market. The materials used to manufacture the IBC Vent Valve are non-toxic and meet current ISO biocompatible tripartite standards using the FDA matrix.

A perfusionist substituting an IBC Vent Valve for an American Omni Vent Valve with his or her cardiotomy reservoir 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

NOV 19 1999

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

Re: K992964
IBC Cardiotomy Vent Valve
Regulatory Class: II (two)
Product Code: MNJ
Dated: August 31, 1999
Received: September 2, 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.

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,

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K992964

Device Name: IBC Cardiotomy Vent Valve

Indications for use:

The Cardiotomy Vent Valve is indicated for use to maintain a low level of vacuum in cardiotomy reservoirs.

(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 K992964

(Division Sign-Off)

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