K963156

510(k) SUMMARY

NOV 1 4 1997

IBC Cardiac Suction Wand

The IBC Cardiac Suction Wand is a single use, sterile, disposable surgical instrument intended for the collection of blood and other fluids from the surgical field for return through the cardiotomy system during open heart surgery. It is substantially equivalent to the Research Medical Intracardiac Sucker marketed by Research Medical, Inc..

TABLE OF COMPARISON

CHARACTERISTIC	IBC CARDIAC SUCTION WAND	RESEARCH MEDICAL INTRACARDIAC SUCKER
Components	4	4
Tube	Passivated Stainless Steel	Passivated Stainless Steel
Handle	Overmolded Plastic	Overmolded Plastic
Tubing Adapter	Overmolded Plastic	Molded and Bonded Plastic
Cardiac Tip	Molded Plastic Bonded	Molded Plastic Bonded
Proximal Bend Angle	35 Degrees	35 Degrees
Distal Bend Angle	35 Degrees	35 Degrees
Blood Compatibility	Non-Hemolytic	Non-Hemolytic
Sterilization	Ethylene Oxide	Ethylene Oxide
Toxicity	Tripartite Guidelines	Tripartite Guidelines

DISCUSSION OF SIMILARITIES AND DIFFERENCES

The IBC Cardiac Suction Wand is in most ways identical to the Research Medical Intracardiac Sucker. The blue tint of the handle is slightly different, the IBC stainless steel tube has a larger flow diameter and is electropolished as well as passivated, the IBC tubing adapter is overmolded and the Research Medical is molded and bonded. The net effect of these differences are primarily cosmetic. Occasionally, surgeons use the suction wand to retract tissues for visibility purposes. The IBC tube provides additional strength for this practice which is not recommended.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. H. David Shockley, Jr.
Official FDA Correspondence
International Biophysics Corporation
4020 S. Industrial Drive
Suite 160
Austin, Texas 78744

NOV 14 1997

Re: K963756
IBC Cardiac Suction Wand
Regulatory Class: II (Two)
Product Code: DTS
Dated: August 13, 1997
Received: August 18, 1997

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 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" (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/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

Enclosure

510(k) Number (if known): K963756

Device Name: IBC Cardiac Suction Wand

Indications For Use:

The IBC Cardiac Suction Wand is intended for use by a Cardiac Surgeon during open heart surgery for the collection of blood and other fluids from the sterile surgical field for filtering and return to the patient via the Cardiotomy line. It is also intended for use by surgeons for the removal of waste fluids from the surgical field.

(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 K963756

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)