K965016

Gibeck

Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck Iso-Gard™ Filter Angled/ Iso-Gard™ Filter Straight

DEC - 2 1997

Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Iso-Gard Filter Angled/Iso-Gard Filter Straight are breathing circuit bacterial filters intended to remove microbiological and particulate matter from the gases in the breathing circuit as described in 21 CFR 868.5260. This product is substantially equivalent to the Dryden Mini Bacteria Filter.

The Iso-Gard Filter Angled/Iso-Gard Filter Straight are similar in design and function to the Dryden Mini Bacteria Filter with reduced size, dead space and lighter weight. The Iso-Gard Filter Angled/Iso-Gard Filter Straight incorporates a luer port in the housing to allow for connection of carbon dioxide or pressure monitoring equipment. The Iso-Gard Filter Angled also incorporates an angled housing to allow for the option of omitting the connection of angled patient connectors. The bacterial/viral filtration efficiency of the filter medium is 99+% for both the Iso-Gard Filter Angled/Iso-Gard Filter Straight and the Dryden Mini Bacteria Filter.

The principal difference between the Iso-Gard Filter Angled/Iso-Gard Filter Straight and the Dryden Mini Bacteria Filter is the size of the device. This change is not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should this change significantly affect the safety or effectiveness of the device when used as labeled.

Submitter/Contact Person

12/10/96
Date

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A Member of the Gibeck Group

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC - 2 1997

Ms. Chyrell Saunders
Gibeck, Inc.
P.O. Box 36430
Indianapolis, Indiana 46236

Re: **K965016**
Iso-Gard Filter Angled/Iso-Gard Filter Straight
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: August 22, 1997
Received: September 4, 1997

Dear Ms. Saunders:

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

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

Enclosure

Indications For Use

501(k) Number (if known): K965016

Device name: Iso-Gard Filter Angled/Iso-Gard Filter Straight

Indications For Use: Intended to remove microbiological and particulate matter from the gases in the breathing circuit.

(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 K965016

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)