

MAR 28 2000

K993060

Gas Filter

510(k) Submission: Component 0008-00313
Predicate Device: Gish Biomedical Gas Filter (K832935)

Intended Use:

The proposed gas filter and the Gish filter are intended to remove particulate matter from the gases flowing into the cardiopulmonary bypass circuit.

Principle of Operation/Technology:

During extracorporeal circulation, it is necessary to adequately provide for blood gas maintenance. Typically, the circuitry that enables gas to be introduced to the blood flow contains a gas filtration device. The proposed gas filter and the Gish filter each utilize a physical barrier that mechanically entraps and separates particulate matter from the flow of gas, thereby preventing such matter from entering into, and contaminating the extracorporeal fluid.

Design/Materials:

The proposed device and the Gish filter are each made of materials that are commonly used in cardiopulmonary bypass devices and circuits. The Gish filter is made of ABS, and Versapor (Acrylic); the proposed devices are made of hydrophobic laminated glass media, Versapor (Acrylic) and polypropylene. The differences in these materials raise no new issues of safety or effectiveness.

Performance:

Evaluations of the gas filter demonstrated an acceptable level of performance.

Note: Filtration efficiency not tested due to certification from original manufacturer of 99.98% efficiency of 0.3 μm particle removal.

Conclusion:

In summary, the gas filter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, and performance to the cleared Gish filter (K832935).



MAR 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olson Medical Sales, Inc.
C/O Mr. Gary A. Courtney
Regulatory Affairs Associate
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K993060
Gas Filter 0008-00313
Regulatory Class: II (two)
Product Code: JOD
Date: January 7, 2000
Received: January 10, 2000

Dear Mr. Courtney:

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.

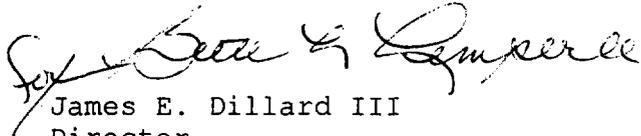
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Gary A. Courtney

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,

A handwritten signature in cursive script, appearing to read "James E. Dillard III".

James E. Dillard III
Director
Division of Cardiovascular, Respiratory,
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K993060

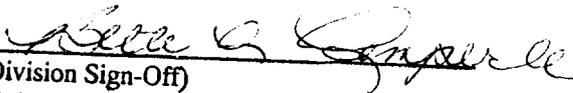
Device Name: Components For Cardiovascular Procedure Kit – Gas Filter

Indications For Use:

The Gas Filter is intended to remove particulate matter from medical gases flowing into the cardiopulmonary bypass circuit for periods up to 6 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 of Cardiovascular, Respiratory,
and Neurological Devices

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