

K021020

Section II 510(k) Summary
Terumo Gas Filter
Terumo Cardiovascular Systems

JUN 1 0 2002

Terumo Gas Filter

Submitter Information:

Name and Address:

Terumo Cardiovascular Systems Corp.
28 Howe Street
Ashland, MA 01721

Contact Person:

Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: March 13, 2002

Device Names:

Proprietary Name: Terumo Gas Filter
Common Name: Gas Filter
Classification Name: Filter, Bacterial, Breathing-Circuit

Predicate Device:

The Terumo Gas Filter that is the subject of this premarket notification is substantially equivalent to the predicate device, Gasline Filter (Gish Biomedical), which is legally marketed and was cleared by FDA on November 22, 1983 (K832935).

Intended Use:

The Terumo Gas Filter is intended to remove particulate matter from the gases flowing into the cardiopulmonary bypass circuit.

The Terumo Gas Filter is intended for use in procedures lasting up to 6-hours in duration.

Principles of Operation and 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 Terumo Gas Filter utilizes 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 and Materials:

The Terumo Gas Filter is a 47mm borosilicate glass microfiber screen that is contained within a polypropylene housing. The filter provides a 13 cm² filtration area which yields a filtration efficiency level of greater than 99% of particles greater than 0.2 μm. The housing measures 2.16 inches in length (nominal) and 2.05 inches in diameter width (nominal). The inlet and outlet ports are identical (device is bi-directional), and each port measures .320 - .438 inches to allow for the connection of tubing from 1/4" to 3/8".

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Performance Evaluations:

The Terumo Gas Filter submitted in this premarket notification was subjected to the following tests to demonstrate the safety and efficacy of the device:

- Visual Analysis
- Leakage Testing/Mechanical Integrity
- Filtration Efficiency

Substantial Equivalence Comparison:

The Terumo Gas Filter is substantially equivalent to the predicate Gasline Filter (Gish) as follows:

- Intended Use: Both the Terumo Gas Filter and the predicate Gasline Filter are intended to remove particulate matter from the gases flowing into the cardiopulmonary bypass circuit.
- Principles of Operation and Technology: The Terumo Gas Filter and the predicate Gasline Filter each utilize the same technologies in the operation of the devices. The filters 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 and Materials: The design of the Terumo Gas Filter and the predicate Gasline Filter is essentially the same. Both devices are comprised of a filter material that is encased in a hardshell housing that has inlet and outlet ports to facilitate the flow of gas into and away from the device.

The Terumo device is constructed from polypropylene and borosilicate glass micro-fibers, whereas the predicate device is constructed from acrylic co-polymer and ABS. The materials used in the construction of the devices are equivalent relative to device functioning. The difference in these materials does not raise any new issues of safety and/or effectiveness.

- Performance: The Terumo Gas Filter has been demonstrated to be effective in removing >99.99% of particulate matter down to 0.1 μm . The predicate Gasline filter is labeled as effective in removing particulate matter down to .45 microns.

Substantial Equivalence Summary:

In summary, the Terumo Gas Filter and the predicate Gasline Filter are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6} .
- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).
- Performance evaluations were conducted on non-aged devices as well as aged devices for the purpose of demonstrating that the aging process does not adversely impact the performance of the device.

Conclusion:

In summary, the Terumo Gas Filter is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate Gasline Filter (Gish – K832935).

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

Terumo Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney
Senior Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K021020

Trade Name: Terumo Gas Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Filter, Bacterial, Breathing-Circuit
Regulatory Class: Class II (two)
Product Code: CAH
Dated: March 28, 2002
Received: March 29, 2002

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

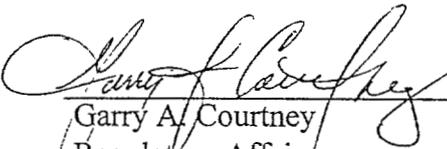
510(k) Number (if known):

Device Name: TERUMO GAS FILTER

Indications For Use:

The Terumo Gas Filter is intended to remove particulate matter from the gases flowing into the cardiopulmonary bypass circuit.

The Terumo Gas Filter is intended for use in procedures lasting up to 6-hours in duration.


Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K021020

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)