

K964908
Sept. 3, 1997

510(k) SUMMARY

A. Name and Address of Submitter

Sorin Biomedical Inc.
17600 Gillette Avenue
Irvine, California 92614-5751

B. Telephone and Fax Numbers of Submitter

Telephone: (714) 250-8320
Fax: (714) 250-1524

C. Name of Contact Person

Richard J. DeRisio
Vice President
Quality & Regulatory Affairs

D. Date Summary was Prepared _____

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510(k) SUMMARY (cont.)

E. Device Name

Trade or Proprietary Name:

VRF 40 Venous Reservoir with Integral Cardiomy Filter

Common Name:

Cardiomy Reservoir, Venous Reservoir with Integral Cardiomy Filter

Classification Name:

**Cardiopulmonary Bypass Blood Reservoir
Cardiopulmonary Bypass Cardiomy Suction Line Blood Filter**

F. Summary of Substantial Equivalence

The VRF40 Venous Reservoir with Integral Cardiomy Filter is judged to be substantially equivalent in intended use, materials, design, and performance characteristics to the Sorin Hardshell Venous Reservoir (HSVRF). The HSVRF was cleared for chest drainage on September 30, 1987 (K872719). The VRF40 was designed for use in chest drainage and is marketed by DIDECO for that intended use outside the United States.

G. Device Description

The VRF40 is a sterile, nonpyrogenic, disposable, hardshell venous reservoir with an integral cardiomy filter. It contains a polyurethane defoamer sponge and outer gross filter screen.

H. Intended Use

The VRF40 is intended to allow for the collection and autotransfusion of shed mediastinal blood following cardiopulmonary bypass procedures or other procedures where shed blood is expected.

I. Summary of Comparison of Technological Characteristics

The technological characteristics of the VRF40 is similar to the Sorin Hardshell Venous Reservoir with respect to chest drainage autotransfusion. These devices have a similar number of cardiomy inlet ports, have similar filter elements, and are similar in setup and use for chest drainage.

510(k) SUMMARY (cont.)

J. Summary of Nonclinical Tests

Substantial equivalence was based on a comparison of test results from the following *in vitro* physical and functional tests:

Physical Tests

Vacuum Integrity

Functional Tests

Hemolysis

Residual Volume

Filter Pressurization

All testing was conducted on nonaged, sterile devices. Test results show similar performance characteristics between the VRF40 and the Sorin Hardshell Venous Reservoir with respect to the expanded use of chest drainage autotransfusion.

Biocompatibility

Biocompatibility testing was previously performed on a finished, sterilized device in accordance with the Tripartite Guidelines for Biocompatibility testing for short term blood contacting materials. All test results were comparable to the negative control groups. Therefore, the materials used in the VRF40 are considered acceptable for their intended use.

K. Conclusions

Based upon the above information, Sorin Biomedical Inc. concludes that the VRF40 Venous Reservoir with Integral Cardiotomy Filter is substantially equivalent to the Sorin Hardshell Venous Reservoir for use in chest drainage autotransfusion or any procedure where shed blood is expected.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Paul Butorac
Manager, Quality Engineering Department
Sorin Biomedical, Inc.
17600 Gillette Avenue
P.O. Box 19503
Irvine, California 92713-9503

SEP - 3 1997

Re: K964908
VRF40 Venous Reservoir with Integral Cardiotomy Filter
Regulatory Class: II (Two)
Product Code: 74 DTN
Dated: June 10, 1997
Received: June 12, 1997

Dear Mr. Butorac:

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 (Pre-market 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 pre-market 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. Paul Butorac

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

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510(k) Number (if known): K964908

Device Name: VRF40 Venous Reservoir with Integral Cardiomy Filter

Indications for Use: The VRF40 Venous Reservoir with Integral Cardiomy Filter is intended for use in CPB circuits and postoperative blood salvage procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 964908

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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