

NOV - 5 1999

K990103

510(k) Summary
MONOLYTH C Hollow Fiber Membrane Lung
with Integrated Softshell Venous Reservoir

1. Submitter

Sorin Biomedical Inc.
17600 Gillette Avenue
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U.S.A.

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Date Summary Prepared: October 22, 1998

2. Name of Device

Trade Names: MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell
Venous Reservoir
CVR Softshell Venous Reservoir
Common Names: Hollow Fiber Oxygenator
Softshell Venous Reservoir

3. Device Classification:

Class III: 21 CFR 870.4350 Cardiopulmonary Bypass Oxygenator
Class II: 21 CFR 870.4400 Cardiopulmonary Bypass Blood Reservoir —

4. Device Intended Use and Description

The MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir is intended for use in an extracorporeal bypass circuit. The device provides oxygenation and removal of carbon dioxide from venous or suctioned blood. The integral heat exchanger provides blood temperature control, allows for the use of hypothermia, or aids in the maintenance of normothermia during surgery. The integral venous reservoir is intended for use as a storage reservoir for blood. The device is indicated for use with blood flows of 1.0 - 8.0 liters per minute (LPM). The MONOLYTH C 600 and the MONOLYTH C 1200 have been tested for 6 hours of continuous use. Use longer than 6 hours is not advised.

The MONOLYTH C is a high efficiency hollow fiber oxygenator with integral heat exchanger and a softshell venous reservoir. The venous reservoir is available both integrated with the device or as a separate device.

The oxygenator consists of microporous capillary polypropylene fibers wound around a perforated core in a crossed mat configuration. The fiber bundle has a surface area of approximately 2.2 m². The blood path is around the outside of the fibers, while the gas path is through the lumens of the fibers. An arterial temperature probe is located close to the arterial outlet. The arterial sampling line contains an integrated one-way valve to prevent accidental air injection. The gas outlet is equipped with a capnograph connector for CO₂ measurement. The gas outlet cap has a safety anti-occlusion feature to aid in gas venting.

A line between the gas module and the venous reservoir facilitates gravity priming of the system and allows for recirculation. This line is accessed via a high-pressure stopcock located at the lower portion of the membrane. The stopcock provides access to arterial blood throughout the procedure for cardioplegia, perfusion, or blood concentration.

The heat exchanger is on the venous side of the device and is comprised of epoxy-coated pleated stainless steel. The heat exchanger has a surface area of 0.17 m².

The softshell venous reservoir is attached to a rigid external shell which is mounted on top of the oxygenator module. The softshell venous reservoir is a soft, flexible plastic bag with an integral screen and a rigid backplate. The backplate contains two inlet ports, a recirculation port, and a temperature probe port. The reservoir collects blood coming from venous return and from the cardiotomy reservoir. Blood from venous return and from the cardiotomy reservoirs is collected via separate inlet ports. Blood is then filtered through the screen to deflect air bubbles to the top of the reservoir. Bubbles may be purged through a double purge line with an additional luer port located at the top of the reservoir, which join together into a common line. The common purge line contains a one-way valve which prohibits air from returning into the reservoir. The temperature port, located below the venous inlet port, is designed to receive a YSI series 400 compatible probe.

The venous reservoir has one outlet line located at the bottom center of the bag. A 1/4-inch recirculation line is attached to a port on the back of the reservoir. This line may be connected to the arterial outlet or the recirculation port of the oxygenator to recirculate blood back to the venous reservoir.

5. Substantial Equivalence

The MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir is substantially equivalent to the Sorin Monolyth Integrated Membrane Lung (510(k) K922933, cleared November 30, 1992) and the Monolyth Venous Reservoir (510(k) K933481, cleared November 12, 1993), both manufactured by Sorin Biomedical Inc. The intended use, design, materials, and manufacturing processes of the MONOLYTH C are substantially equivalent to those of the predicate devices.

The intended use of the MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir is identical to the intended use of the Monolyth Integrated Membrane Lung. Both devices are intended for the adult population who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation.

The oxygenator of the MONOLYTH C Integrated Membrane Lung with Integrated Softshell Venous Reservoir is identical to the oxygenator used in the MONOLYTH Integrated Membrane Lung. The MONOLYTH Integrated Membrane Lung has been modified to attach a softshell venous reservoir in place of the hardshell venous/cardiectomy reservoir. The softshell venous reservoir is substantially equivalent in intended use, design, and manufacturing processes as the Monolyth Venous Reservoir (MVR).

6. Testing Summary

In vitro studies were conducted to evaluate the performance characteristics and mechanical integrity of the Monolyth C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir and the CVR Softshell Venous Reservoir. Oxygenator *in vitro* testing were performed and presented in the original 510(k) (K922933): gas exchange study (oxygen transfer and carbon dioxide transfer), operating blood volumes, blood side pressure drop, heat exchanger study, mechanical integrity study (blood path and heat exchanger burst and leak tests).

To address the modification to the oxygenator/reservoir, additional *in vitro* testing was performed on aged and unaged MONOLYTH C Hollow Fiber Membrane Lung with Integrated Membrane Lung with Softshell Venous Reservoir and on CVR Softshell Venous Reservoirs. Product performance testing included hemolysis and cell depletion, air removal efficiency, physical integrity, minimum operating volume, fill capacity, and flow path testing. Results of the tests showed that the MONOLYTH C is substantially equivalent to the predicate devices and is acceptable for its intended use.

Biocompatibility tests were performed using representative samples (whole units, subassemblies, and components) based on the intended use of the device (external-communicating device, circulating blood contact, limited contact duration (≤ 24 h)). Results of the tests showed that the device is biocompatible and therefore is acceptable for its intended use.

7. Conclusion

Based on the information provided, Sorin Biomedical Inc. concludes that the MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir is substantially equivalent to the predicate devices and is acceptable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynne Leonard
Manager, Regulatory Submissions
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K990103
Monolyth C 600 and 1200 Hollow Fiber Membrane Lung Integrated
Softshell Venous Reservoir
Regulatory Class: III (Three)
Product Code: DTZ
Dated: September 9, 1999
Received: September 10, 1999

Dear Ms. Leonard:

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.

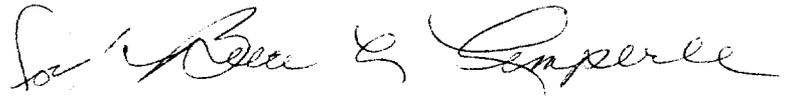
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



Celia M. Witten, Ph.D., M.D.
Acting Director

Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990103

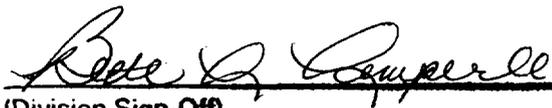
Device Name: MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir

Indications for Use:

The MONOLYTH C Hollow Fiber Membrane Lung with Integrated Softshell Venous Reservoir is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. The device provides oxygenation and removal of carbon dioxide from venous or suctioned blood. The integral heat exchanger provides blood temperature control, allows for the use of hypothermia, or aids in the maintenance of normothermia during surgery. The integral softshell venous reservoir is intended for use as a storage reservoir for blood. The device is indicated for use with blood flows of 1.0 to 8.0 liters per minute (LPM). The MONOLYTH C 600 and the MONOLYTH C 1200 have been tested for 6 hours of continuous use. Use longer than 6 hours is not advised.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990103

prescription ✓