

K980600

AUG 12 1998

510(k) Summary  
Dideco S.p.A.  
D903 Avant Hollow Fiber Oxygenator

**1. SUBMITTER**

Dideco S.p.A.  
86, Via Statale 12 Nord  
41037 Mirandola (MO)  
Italy

Contact Person:  
Mr. Marco Mantovani  
Quality Director  
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Date Summary Prepared: February 13, 1998

**2. NAME OF DEVICE**

Trade Name: D903 Avant  
Common Name: Hollow fiber oxygenator

**3. DEVICE CLASSIFICATION**

Class III: 21 CFR 870.4350 Cardiopulmonary bypass oxygenator  
Class III: 21 CFR 870.4230 Cardiopulmonary bypass defoamer  
Class II: 21 CFR 870.4400 Cardiopulmonary bypass blood reservoir

**4. DEVICE INTENDED USE AND DESCRIPTION**

The D903 Avant 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 use of hypothermia, or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect the blood aspirated from the operating field during surgical procedures and the blood

from patients' veins during normal operation, to always assure the proper oxygenation capability of the device.

The Dideco D903 Avant membrane oxygenator is a high efficiency membrane oxygenator of hollow fiber design with an integral heat exchanger and an attached hardshell cardiotomy/venous reservoir. The device will be available both as an integrated device and as separate devices; a single sterile oxygenator module and the venous/cardiotomy reservoir.

The fiber bundle within the oxygenator consists of a polycarbonate core wound with microporous polypropylene hollow fibers. The core is encapsulated on both ends with polyurethane and contained within a polycarbonate housing.

Two versions of the oxygenator will be offered in two configurations having different affective gas exchange surface. The first has an effective gas exchange surface of 1.6 m<sup>2</sup>, while the latter has an effective gas exchange surface of 2.0 m<sup>2</sup>.

The integral heat exchanger is comprised of a grooved and plated stainless steel sheet. The hardshell cardiotomy/venous reservoir of the integrated version is attached to the top of the oxygenator by means of a molded fitted joint and is comprised of a rigid polycarbonate housing with an internal support. The filtering system surrounds the internal support. Suctioned blood enters the cardiotomy section by two rotatable turrets equipped with 3/8" and 1/2" connectors. The blood enters the reservoir by gravity drainage from the cardiotomy, through the venous inlet placed in the bottom of the reservoir or by means of a recirculation line (allowing oxygenated blood to be recirculated and purged back to the reservoir).

A self-purging four-way stopcock located beside the oxygenation module of the D903 Avant allows for arterial and venous blood sampling. The blood sampling system consists of three coiled PVC tubes connected to a four-way stopcock. The tubes allow for either sampling or purging of arterial and venous blood or delivery of drugs into the venous line.

The D903 Avant includes arterial and venous temperature probe sites for monitoring of blood temperature. A holder is available for use with the oxygenator. The holder is comprised of a stainless steel rotating arm secured to the IV pole by means of a knob. This allows for independent rotation of the device. On the bottom of the holder are two integrated Hansen water connectors securing the Oxygenator in a locked position.

Venous blood flows into the hardshell venous reservoir where the air is constantly evacuated through the integrated filter. The blood volume into the reservoir is monitored by a graduation on the hardshell. The suctioned blood flows into the cardiotomy reservoir mechanically separated from the venous reservoir. The separate cardiotomy section of the Avant allows the suctioned blood from the operating field to spontaneously debubble before it enters into the venous reservoir section.

Blood is pumped out of the venous reservoir through tubing in a pump head and pumped into the bottom of the heat exchanger (blood side) of the oxygenator module. The blood then flows in an upward direction through the stainless steel heat exchanger, where the blood temperature is easily controlled by adjusting the temperature of the circulating water. After the rewarming or cooling, venous blood flows from the inside of the hollow fiber bundle in a downward direction and towards the outside of the bundle core. The oxygenated blood exits the bundle core through the arterial outlet. Gas flows through the interior of the hollow fibers and blood flows over the exterior. Gas exchange occurs with blood flow outside the polypropylene hollow fibers. As the gas and the blood flow in opposite directions, oxygen and carbon dioxide will diffuse across the membrane. By regulating the concentration of oxygen and controlling the gas flow, the amount of oxygen and carbon dioxide transfer can be controlled.

## 5. SUBSTANTIAL EQUIVALENCE

The D903 Avant is substantially equivalent to the following currently marketed integrated oxygenators/reservoirs in commercial distribution (cleared on 5/11/93 - 510(k) K922933):

<u>Device Name</u>	<u>Device Designation</u>	<u>Manufacturer</u>
MONOLYTH	MONOLYTH	Sorin Biomedical Inc. 17600 Gillette Avenue P.O. Box 19503 Irvine, CA 92713-9503 U.S.A.

The claim of substantial equivalence is based on the following criteria:

The D903 Avant is an adult Hollow Fiber Oxygenator with integral hardshell venous reservoir and heat exchanger, like the predicate device. The basic function of all integrated reservoir oxygenators is the same. That is, a combination blood-gas exchange device with a separate reservoir section. Blood is drawn from the venous reservoir and pushed through the heat exchanger and gas modules via an external pump. This flow is referred to as 'post-pump' and is the same for both D903 Avant and Monolyth.

The operating principles and control mechanisms are exactly the same for both the D903 Avant and the Monolyth. The gas exchange module of both devices is comprised of microporous polypropylene fibers with blood flow around the outside of the fibers and oxygen flows within the bundle of the fibers. The D903 Avant utilizes the same fiber material type and blood flow path as the Monolyth and both the oxygenators contain an integrated heat exchanger comprised of corrugated stainless steel sheet.

The indications for use are the same for both D903 Avant and Monolyth. Both devices are intended for the adult population who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation.

The same probes are used for all devices. A bayonet fitting blood temperature port is placed in both the arterial and venous lines. Temperature probe sites are compatible with YSI 400 series monitoring systems.

## 6. TESTING SUMMARY

*In vitro* studies of the Dideco D903 Avant Membrane Oxygenator were performed by Dideco to evaluate the performance characteristics and mechanical integrity of the D903 Avant oxygenator. Product testing included gas transfer, heat transfer, operating and residual volumes, blood-side pressure drop, gas-side pressure drop, hemolysis/cell changes, mechanical integrity, filtration and defoaming efficiency, reservoir venous inlet flow capacity and backpressure, breakthrough time and volume, filter pressurization and residual volumes. The Dideco *in vitro* protocols used were based on the proposed 1991 AAMI-ISO Draft Standard for blood-gas oxygenators, where applicable.

Clinical studies were also performed on a total of ten patients using the Avant D903 Hollow Fiber Oxygenator. Satisfactory arterial and venous PO<sub>2</sub>, PCO<sub>2</sub>, and pH were reported during CPB for all study patients. The blood flow rates ranged from 2.9 l/min to 5 l/min. The gas flow rates during CPB ranged from 1.8 l/min to 4.0 l/min with an average of 2.72 l/min at all time points.

Gas composition (FiO<sub>2</sub>) ranged between 35 and 100% and averaged 60%. Venous pO<sub>2</sub> ranged from 32.3 to 66.9 with the average being 43 for all time points. Arterial pO<sub>2</sub> was adequately maintained throughout the procedure ranging from 111 to 657 mmHg. The average arterial pO<sub>2</sub> was 324.1 mmHg.

Hematological data were collected for evaluation of blood trauma. Increases of plasma free hemoglobin and changes of formed elements such as platelets, Overall general results showed that the average plasma free hemoglobin was about 40.6 mg/dl at the end of cardiopulmonary bypass. Platelet concentration followed normal cardiopulmonary bypass levels, decreasing during surgery and increasing post-operatively. A similar pattern was demonstrated for red blood cells which decreased on average to about 20% to 30% below normal at 60 minutes into the procedure and then rebounded back to about 75% of normal at 72 hours post-bypass. The white blood cell count dropped during surgery and then rebounded back up to normal or slightly greater than normal values.

#### Test Results and Conclusions

Test Results	Conclusions
Oxygen transfer	The oxygen transfer rates were evaluated at blood flow rates of 4, 6 and 8 LPM. The results compare favorably with the predicate device.
Carbon Dioxide Transfer	The carbon dioxide transfer rates were evaluated at blood flow rates of 4, 6, and 8 LPM. The results are similar to the predicate device.

Test Results	Conclusions
Operating Blood Volumes	The operating blood volumes for the D903 Avant, including static prime, post-use recovered and retained volume were evaluated. Results compares favorably to the predicate device. The D903 Avant has a reduced retained volume respect the predicate device, a lower priming volume is desirable in that it results in less haemodilution to the patient and decreased risk of donor transmitted disease.
Blood Side Pressure Drop	The blood path pressure drop data were recorded during gas transfer testing at T=0 hours and T=6 hours. The results indicated no significant change in blood path pressure drop.
Heat Exchange Study	Heat exchange performance compares favorably to other oxygenators on the market.
Hemolysis/Cell Depletion	The hemolysis and cell change results were characterized by comparing the D903 Avant to the predicate device for plasma hemoglobin, index of hemolysis, white blood cell counts/percent depletion, red blood cell counts/percent depletion and platelet counts/percent depletion. There were no statistically significant differences ( $p > 0.05$ ) in cell depletion and haemolytic characteristics between the D903 Avant and the predicate device.
Mechanical Integrity Study	There were no signs of leakage or pressure decay throughout the test periods for either the blood path or the heat exchanger water path.
Breakthrough Time and Volume	Time and volumes of blood required to breakthrough the cardiotomy screen of the D903 Avant cardiotomy reservoir at 1 LPM were carried out. The results were compared to data obtained for the Monolith reservoir. There were statistically significant differences ( $p < 0.05$ ) both time and volume requested to breakthrough the cardiotomy screen, the D903 Avant showed a lower apparition time and volume than the predicate device. A reduced breakthrough time and volume is desirable as it results in lower fluid losses during priming and perfusion phases.

Test Results	Conclusions
Filter Pressurization and Residual Volumes	The filter pressurization and residual volume characteristics of the D903 Avant cardiotomy reservoir were evaluated. The results were compared to data obtained for the Monolyth reservoir. The results of this study indicate that the filter pressurization and residual volume of the D903 Avant are comparable to the Monolyth's one.
Filtration Efficiency	The filtration efficiency characteristics of the D903 Avant cardiotomy reservoir was evaluated. The results were compared to data obtained for the Monolyth reservoir. The results of this study indicate that the filtration efficiency of both devices satisfy the requirements of ANSI/AAMI BF7 - 1982 (80% particles removal at 40 microns).
Reservoir Venous Inlet Flow Capacity and Venous Backpressure	The amount of flow attained by the venous inlet of the unit while maintaining 2 litres reservoir volume at various head heights above the reservoir inlets and the pressure exerted in the venous return line of the D903 Avant cardiotomy reservoir were evaluated. The results were compared to data obtained fro the Monolyth reservoir. The results of this study indicate that the venous inlet flow capacity and backpressure of the D903 Avant are comparable to the Monolyth's one.
Conclusions	Based on the above information and the clinical studies, Dideco S.p.A. concludes that the D903 Avant demonstrates equivalence to other legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 12 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DIDECO S.P.A.  
c/o Ms. Mary McNamara-Cullinane  
Staff Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

Re: K980600  
Dideco D903 Avant Hollow Fiber Oxygenator  
Regulatory Class: II  
Product Code: JOW  
Dated: May 13, 1998  
Received: May 14, 1998

Dear Ms. McNamara-Cullinane:

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 - Ms. Mary McNamara-Cullinane

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,



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

Enclosure

510(k) Number (if known): K980600

Device Name: Dideco D903 Avant Hollow Fiber Oxygenator

Indications For Use:

The Dideco D903 Avant Hollow Fiber Oxygenator is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation . It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiectomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patients' veins during normal operation to assure the proper oxygenation capability of the device. The D903 Avant is intended to be used for six hours or less.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K980600