K043323

510(k) SUMMARY

SUBMITTER:

Dideco S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

Luigi Vecchi
Phone: 011 39 0535 29811
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DATE PREPARED:

December 1, 2004

DEVICE TRADE NAME:

D 905 EOS: Hollow Fiber Oxygenator With Integrated Hardshell Venous/Cardiotomy Reservoir

COMMON NAMES:

Hollow Fiber Oxygenator with Hardshell Venous/Cardiotomy Reservoir
Hollow Fiber Oxygenator
Hardshell Venous/Cardiotomy Reservoir

CLASSIFICATION NAMES:

Cardiopulmonary Bypass Oxygenator
Cardiopulmonary Bypass Heat Exchanger
Cardiopulmonary Bypass Blood Reservoir
Cardiopulmonary Bypass Defoamer

PREDICATE DEVICES:

D 903 Avant 2 Ph.I.S.I.O. Adult Hollow Fiber Oxygenator with Integral Hardshell Cardiotomy / Venous Reservoir with Biocompatible Treatment Surface (Ph.I.S.I.O.) (K033323)

Cobe Optimin Hollow Fiber Membrane Oxygenator (K991452)

DEVICE DESCRIPTION:

The D 905 EOS Hollow Fiber Oxygenator With Integrated Hardshell Venous/Cardiotomy Reservoir (hereafter referred to as the D 905 EOS) is a high efficiency microporous hollow fiber membrane oxygenator integrated with an heat exchanger and connected to an hardshell venous/cardiotomy reservoir. The device is a modified version of the currently marketed D 903 Avant 2 Ph.I.S.I.O (K033323) predicate device (hereafter referred to as the Avant Ph.I.S.I.O.). The modification is limited to an overall reduction in the size of the device. The reduction in size enables the device to be better suited for the pediatric and small adult patient population.

INDICATION FOR USE:

The D 905 EOS Hollow Fiber Oxygenator With Integrated Hardshell Venous/Cardiotomy Reservoir hereinafter called the D 905 EOS, is a sterile, nonpyrogenic device intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters/minute. The device provides oxygenation and carbon dioxide removal from venous or suctioned 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 cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from the patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. Following intraoperative use, the reservoir is used for the collection and autotransfusion of shed blood and/or chest drainage. The device is intended to be used for 6 hours or less. Contact with blood for longer periods is inadvisable.

TECHNOLOGICAL CHARACTERISTICS:

The D 905 EOS is essentially identical to the Avant Ph.I.S.I.O. predicate device with respect to design, materials, biocompatibility of the $PmMI_2$ coating., operating principles, technological characteristics and manufacturing process. The hardshell cardiotomy/venous reservoir present in both D 905 EOS and Avant Ph.I.S.I.O. share the same technological characteristics, operating principles, materials and basic design of the Avant Ph.I.S.I.O. except for a reduction of its dimensions. The D 905 EOS oxygenating module shares the same basic design, operating principles and control mechanisms of the Avant Ph.I.S.I.O. module. The only modifications consist of a reduction of its dimensions and consequently in less hollow fiber membrane material with respect to the Avant Ph.I.S.I.O. predicate device. These differences make the D 905 EOS more suited for smaller adult and pediatric patients like the Cobe Optimin predicate device. The D 905 EOS is substantially equivalent to the Cobe Optimin predicate device in intended use, patient population and performance specifications.

The coating of the oxygenating module is identical to the phosphorylcholine coating used on the Avant Ph.I.S.I.O. predicate device.

The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing were performed on the D 905 EOS. (accelerated aging). The device aged up to three years was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of this testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 - "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 – "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 and when applicable, following the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the predicate devices and also complying with safety and effectiveness requirements. The device aged up to 3 years was tested for gas transfer characteristics, pressure drop, plasma leakage data, operating blood volumes, heat exchanger performance evaluation, hemolysis/cell depletion, mechanical integrity, venous cardiotomy reservoir characterization (including breakthrough times and volumes, reservoir graduated scale accuracy, residual blood volume, defoaming capacity, filtration efficiency and reservoir housing integrity) and leaching studies characterization. The results of these tests met established

specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the D 903 Avant 2 Ph.I.S.I.O. and on the Cobe Optimin predicate device.
The result of the study showed that the device is comparable to the predicate devices concerning with all characteristics.

MARKETING HISTORY:

Up to now the D 905 EOS is in commercial distribution in Europe since March 2003. No reports of adverse events involving patient safety due to malfunctioning have been received.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the D 905 EOS performs in a manner substantially equivalent to the Cobe Optimin hollow fiber oxygenator with respect to the relevant functional parameters. Furthermore, the D 905 EOS performs in a manner substantially equivalent to the Avant Ph.I.S.I.O. predicate device with respect to the venous reservoir characterization. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible and functional tests demonstrate that its performance is equivalent to the Cobe Optimin predicate device, according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Dideco S.R.L.
c/o Mr. Barry Sall
Parexel International Corporation
195 West Street
Waltham, MA 02451

Re: K043323
D 905 EOS Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir
Regulation Number: 21 CFR 868.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: December 1, 2004
Received: December 2, 2004

Dear Mr. Sall:

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.

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), 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) you may obtain. 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 R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043323

Device Name: Dideco D 905 EOS Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir

Indications For Use:

The Dideco D 905 EOS Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters /minute. 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 cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for 6 hours or less.

Prescription Use X		Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mina R Kirchner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043323