MAY - 2 2003

K031223

510(k) SUMMARY

SUBMITTER:

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

CONTACT PERSON:

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DATE PREPARED:

April 17, 2003

DEVICE TRADE NAME:

SYNTHESIS MIMESYS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous Cardiotomy Reservoir Mimesys Treated (Phosphorylcholine coating hereinafter called PC coating)

COMMON NAME:

Hollow Fiber Membrane Oxygenator/Integrated Arterial Filter/Reservoir

CLASSIFICATION NAME:

Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer/ Cardiopulmonary Bypass Arterial Line Blood Filter

PREDICATE DEVICES:

SYNTHESIS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated

MONOLYTH C 1200 Hollow Fiber Membrane Lung Integrated Softshell Venous Reservoir, CVR 600 and 1200 Sotfshell Venous Reservoir (reservoir only) (K990103),

D 903 AVANT 2 Ph.I.S.I.O. Hollow Fiber Oxygenator (K020351),

MONOLYTH MIMESYS Hollow Fiber Oxygenator (K004001).

DEVICE DESCRIPTION:

SYNTHESIS MIMESYS Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated is a high efficiency microporous hollow fiber membrane oxygenator integrated with a heat exchanger and an arterial filter and connected to a hardshell cardiotomy venous reservoir.

INDICATION FOR USE:

SYNTHESIS MIMESYS Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated (PC coating) hereinafter called the SYNTHESIS MIMESYS is a sterile, nonpyrogenic device intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40µm. SYNTHESIS MIMESYS is an adult oxygenator intended for use in operations on adult patients. SYNTHESIS MIMESYS must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

TECHNOLOGICAL CHARACTERISTICS:

The SYNTHESIS MIMESYS Adult Membrane Oxygenator with Integrated Hardshell Venous/Reservoir, Heat Exchanger and Arterial Filter Mimesys treated (PC coating), is essentially identical to the SYNTHESIS predicate device with respect to operating principles, control mechanisms and biocompatibility of the PC coating. The softshell venous reservoir present in both SYNTHESIS C MIMESYS and MONOLYTH C 1200 predicate device share the same technological characteristics, operating principles and materials. The only modification made to the SYNTHESIS MIMESYS (and other modified version) is the extension of the coating already present on the whole oxygenating module and hardshell venous reservoir (except the filtering media of the reservoir) to the integrated arterial filter and softshell venous reservoir. The coating is identical to the phosphorylcholine coating used on the SYNTHESIS, D 903 AVANT 2 Ph.I.S.I.O. and MONOLYTH MIMESYS predicate devices.

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 was performed on the SYNTHESIS (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 the testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing were 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 the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" when applicable for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. The device was aged up to 3 years and was tested for operating blood volume, mechanical integrity, connection testing, pressure drop, arterial filter characterization, hemolysis/cell depletion, softshell venous reservoir microembolic activity and filtration efficiency, uniformity test and flaking/leaching of the PC coating. The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the SYNTHESIS and SYNTHESIS C predicate device. This 510(k) crosses reference performance data previously submitted in the SYNTHESIS 510k (K022450) for the gas transfer studies, heat exchanger performance evaluation and venous cardiotomy characterization and in the MONOLYTH C1200 510(k) (K990103) for the aspects of the softshell venous reservoir characterization as the above mentioned aspects are not affected by the modification.

The results of the study showed the device characteristics between SYNTHESIS MIMESYS and SYNTHESIS were comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the SYNTHESIS MIMESYS devices perform in a manner substantially equivalent to the predicate devices. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible and functional tests demonstrate that its performance are equivalent to the SYNTHESIS predicate device, according to its intended use. Additional testing has 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

MAY - 2 2003

Dideco S.P.A.
c/o Mr. Barry Sall
Senior Regulatory Consultant
Parexel International
195 West Street
Waltham, MA 02451-1163

Re: K031223
Synthesis Mimesys Adult Membrane Oxygenator with
Integrated Arterial Filter, Mimesys Treated
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: April 17, 2003
Received: April 18, 2003

Dear Mr. Sall:

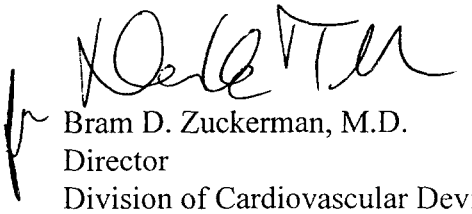
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. 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 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,



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): K031223

Device Name: Synthesis Mimesys Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys Treated

Indications For Use:

Synthesis Mimesys is intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40 µm. Synthesis Mimesys is an adult oxygenator intended for use in operations on adult patients. Synthesis Mimesys must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescritpion Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Otional format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031223