K022450

OCT 22 2002

510(k) SUMMARY

SUBMITTER:

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

CONTACT PERSON:

Luigi Vecchi
Phone: 011 39 0535 29811
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DATE PREPARED:

July 12, 2001

DEVICE TRADE NAME:

SYNTHESIS: 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 with Hardshell Venous/Cardiotomy Reservoir and Integrated Arterial Filter
Hollow Fiber Membrane Oxygenator with Integrated Arterial Filter
Hardshell Venous/Cardiotomy 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:

D 903 Avant 2 Ph.I.S.I.O. Adult Hollow Fiber Oxygenator Oxygenator with Integral Hardshell Cardiotomy / Venous Reservoir with Biocompatible Treatment Surface (Ph.I.S.I.O.) (K020351)

D 734 Micro 40μ Adult Arterial Filter with 40μ Screen (K952270)

DEVICE DESCRIPTION:

The Synthesis 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 an heat exchanger and with an arterial filter and connected to a an hardshell venous/cardiotomy reservoir.

INDICATION FOR USE:

The Synthesis Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated (PC coating) hereinafter called the Synthesis, 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/temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40 μm. Synthesis is an adult oxygenator intended for use in operations on adult patients. Synthesis must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

TECHNOLOGICAL CHARACTERISTICS:

The Synthesis adult membrane oxygenator with Integrated hardshell venous/cardiotomy reservoir, heat exchanger and arterial filter, is essentially identical to the D 903 Avant 2 Ph.I.S.I.O. predicate device with

respect to operating principles, control mechanisms and biocompatibility of the $PmMI_2$ coating. The hardshell cardiotomy/venous reservoir present in both Synthesis and Avant Ph.I.S.I.O. share the same technological characteristics, operating principles and materials. The only modification made on the reservoir consists of a complete revision of the cardiotomy filter geometry and housing design. The Synthesis with reference to the integrated arterial filter is also substantially equivalent to the D 734 Micro 40μ predicate device with respect to the expected main function given to an ordinary arterial filter. The coating is identical to the phosphorylcholine coating used on the D 903 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 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 this 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 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, arterial filter characterization (including filtration efficiency and air removal), venous cardiotomy reservoir characterization (including breakthrough times and volumes, reservoir graduated scale accuracy and residual blood volume, defoaming capacity and filtration efficiency and leaching studies and blood compatibility characterization. The results of this 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 D 734 Micro Arterial Filter 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 Synthesis is in commercial distribution in Europe since January 2002 and currently about 150 units have been placed on the market. No reports of adverse events involving patient safety due to malfunctioning have been received.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the Synthesis performs in a manner substantially equivalent to the D 903 Avant 2 Ph.I.S.I.O. adult hollow fiber oxygenator with respect to the relevant functional parameters. Furthermore the Synthesis performs in a manner substantially equivalent to the D 734 Micro 40 μ arterial filter predicate device with respect to the filtration efficiency and air handling. Data collected show that the feature of integration of the arterial filter to the oxygenating module is advantageous in terms of lower operating blood volumes during priming procedures. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible and functional tests demonstrate that its performance are equivalent to the D 903 Avant Ph.I.S.I.O. 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

OCT 22 2002

Dideco S.p.A.
c/o Mr. Barry Sall
Parexel International Corporation
195 West Street
Waltham, MA 02451-1163

Re: K022450
Synthesis Adult Membrane Oxygenator with Integrated Arterial Filter
Regulation Number: 870.4350
Regulation Name: CPB Oxygenator
Regulatory Class: II (two)
Product Code: DTZ
Dated: July 25, 2002
Received: July 26, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

for 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): _____

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

Indications For Use:

The Synthesis 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. The Synthesis is an adult oxygenator intended for use in operations on adult patients. Synthesis 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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BOE

Division of Cardiovascular & Respiratory Devices
510(k) Number K022450

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)