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
Fax: 011 39 0535 25229

DATE PREPARED:

June 30, 2003

DEVICE TRADE NAME:

IDEAL MIMESYS System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter Mimesys Treated (Phosphorylcholine coating hereinafter called PC coating)

COMMON NAME:

Hollow Fiber Membrane Oxygenator with Integrated Arterial Filter and Heat Exchanger,
Venous Defoamer,
Centrifugal Blood Pump

CLASSIFICATION NAME:

Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Arterial Line Blood Filter / Cardiopulmonary Bypass Defoamer/ Non-Roller Type Cardiopulmonary Blood Pump

PREDICATE DEVICES:

IDEAL System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter (K030154)

SYNTHESIS MIMESYS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys Treated (K031223)

SYNTHESIS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys Treated (K022450)

Cobe Cardiovascular REVOLUTION CENTRIFUGAL BLOOD PUMP with PC coating (K030462),

DEVICE DESCRIPTION:

IDEAL MIMESYS System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter Mimesys Treated (Phosphorylcholine coating hereinafter called PC coating) is an extracorporeal hemodynamic and gas exchange support system for extracorporeal perfusion. IDEAL MIMESYS consists of a high efficiency, microporous, hollow fiber membrane oxygenator integrated with a heat exchanger and an arterial filter (Synthesis Mimesys Adult Membrane Oxygenator, K031223) connected to an active venous air removal device (defoamer), a centrifugal pump (Cobe Revolution Centrifugal Blood Pump with PC coating, K030462) and a pump bracket.

INDICATION FOR USE:

IDEAL MIMESYS is a sterile, nonpyrogenic device intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control. IDEAL MIMESYS must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. Ideal Mimesys is intended for use only with the Stöckert Centrifugal Pump Console.

TECHNOLOGICAL CHARACTERISTICS:

The IDEAL MIMESYS System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter Mimesys Treated (Phosphorylcholine coating hereinafter called PC coating), is identical to the IDEAL predicate device with respect to operating principles, control mechanisms and biocompatibility of the PC coating. The only modification made to the IDEAL MIMESYS is the extension of the coating, already present on the oxygenating module, to all blood contact surfaces including the integrated arterial filter, the centrifugal pump, the venous air removal device and connections. The coating is identical to the phosphorylcholine coating used on IDEAL, SYNTHESIS, SYNTHESIS MIMESYS and REVOLUTION CENTRIFUGAL BLOOD PUMP with PC coating 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 substantial equivalence with the predicate device and also compliance with safety and effectiveness requirements. The device was aged up to 3 years and was tested for mechanical integrity, connection testing, pressure drop and microembolic activity of the venous bubble trap, hemolysis/cell depletion, 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 IDEAL predicate device. Considering the modification of the current submission involves the extension of the PC coating to the integrated arterial filter and the IDEAL MIMESYS utilizes the same integrated arterial filter as the SYNTHESIS MIMESYS predicate device, this 510(k) cross references performance data previously submitted in the SYNTHESIS MIMESYS 510(k) (K031223) for the phosphorylcholine coated arterial filter characterization. Furthermore, the extension of the PC coating also affects the centrifugal pump. The IDEAL MIMESYS utilizes the same integrated centrifugal pump as the REVOLUTION PUMP PC COATED predicate device, this 510(k) cross references performance data previously submitted in the REVOLUTION PUMP PC COATED 510(k) (K030462). The oxygenating module with integrated heat exchanger is not affected by the modification. This 510(k) cross references performance data previously submitted in the SYNTHESIS 510(k) (K022450) for the gas transfer studies, oxygenating module pressure drop evaluation, heat exchanger performance evaluation and blood compatibility characterization.

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

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the IDEAL MIMESYS devices perform in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible and functional tests demonstrate that Ideal Mimesys performance are equivalent to the IDEAL 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

JUL 9 2003

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

Re: K032040
Ideal Mimesys System with Integrated Venous Air Removal
Regulation Number: 870.4360
Regulation Name: Non-Roller Type CPB Blood Pump
Regulatory Class: Class III (three)
Product Code: 74 KFM
Dated: June 30, 2003
Received: July 1, 2003

Dear Mr. Sall:

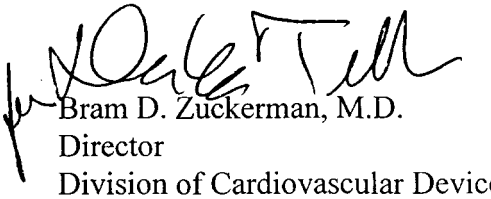
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K032040

Device Name: IDEAL MIMESYS System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Holder, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter Mimesys Treated

Indications For Use:

Ideal Mimesys is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control. Ideal Mimesys must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. Ideal Mimesys is intended for use with the Stöckert Centrifugal Pump Console.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032040