APR - 4 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
Fax: 011 39 0535 25229

DATE PREPARED: March 27, 2002

DEVICE TRADE NAME: Apex Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator

COMMON NAME: Hollow Fiber Oxyenator

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator.

PREDICATE DEVICE: Apex Adult Hollow Fiber Membrane Oxygenator (K014080)
Dideco D 903 Avant 2 Ph.I.S.I.O Adult Hollow Fiber Oxygenator (K020351)

DEVICE DESCRIPTION:

The Apex Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is a cardiopulmonary bypass blood oxygenator with an integral heat exchanger.

INDICATION FOR USE:

The Apex Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

The Apex Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is identical in design, operating principles and control mechanisms to the Apex Adult Hollow Fiber Membrane Oxygenator predicate device. The only modification made to the device is the biocompatible phosphorylcholine coating treatment added to all blood contact surfaces. The fundamental scientific technology is unchanged from the predicate device. The coating is identical to the phosphorylcholine coating used on the D 903 Avant 2 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.

NONCLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:1997 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. Tests were performed on devices accelerated aged to an equivalent of two years real time aging. Sterility, pyrogenicity, EO residuals and package integrity testing were also conducted. The results of testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the requirements of ISO 7199 and the Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff November 13, 2000 to provide the data necessary to demonstrate compliance of the predicate device with safety and effectiveness requirements. The D 903 Avant 2 Ph.I.S.I.O. Oxygenator was aged to 2 years and tested for gas transfer characteristics, pressure drop, plasma leakage data, operating blood volume, heat exchanger performance evaluation, hemolysis/cell depletion, mechanical integrity and leaking/flaking test. The results of these tests met established specifications. The modifications made to the Apex Ph.I.S.I.O. Oxygenator do not affect the performance of the device; therefore, the functional and biocompatibility parameters exhibited by D 903 Avant 2 Ph.I.S.I.O. apply to Apex Ph.I.S.I.O.

CONCLUSION:

The Apex Ph.I.S.I.O. is substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that Apex Ph.I.S.I.O. is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2002

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

Re: K020997
Trade Name: APEX PH.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator.
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: March 27, 2002
Received: March 28, 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,

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

Enclosure

510(k) Number (if known): K020997

Device Name: APEX Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator.

Indications For Use:

The Apex Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular Devices
510(k) Number K020997

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

(Optional format 1-2-96)