NOV 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:

May 24, 2002

DEVICE TRADE NAME:

DHF Hemoconcentrator
available in the DHF Series:
DHF 0,2 Hemoconcentrator: Dideco Newborn-Infant Hemoconcentrator
DHF 0.6 Hemoconcentrator: Dideco Pediatric/Small Adult Hemoconcentrator

COMMON NAME:

Hemoconcentrator

CLASSIFICATION NAME:

Dialyzer, High permeability With or Without Sealed Dialysate System

PREDICATE DEVICE:

Cobe HC 700 Midi Hemoconcentrator (K003023)
Hemocor HPH 400 Hemoconcentrator (K923139)

DEVICE DESCRIPTION:

The Dideco DHF Hemoconcentrator is a hollow fiber type hemoconcentrator consisting of an external transparent housing with two filtrate ports on the cylindrical body and a fiber bundle. These fibers are bonded within the housing with polyurethane. A transparent blood header cap with a male Pos-Lock port is bonded to each end of the housing.

INDICATION FOR USE:

The Dideco DHF Hemoconcentrator is intended for use in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient's physiological hematocrit. The choice of hemconcentrator depends on the protocol being used and required filtration speed. The device is intended to be used for six hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The design, operating principles and control mechanisms are exactly the same for the DHF 0.2 Hemoconcentrator and for the Hemocor HPH 400 Hemoconcentrator (K923139) predicate device. The design, operating principles and control mechanisms are exactly the same for the DHF 0.6 Hemoconcentrator and for the Cobe HC 700 Midi Hemoconcentrator (K003023) predicate device. The

basic function of all the above mentioned hemoconcentrators is the same. That is, the removal of excess fluid from patient's blood during or after cardiopulmonary bypass procedures resulting in hemoconcentration and restoring of patient's physiological hematocrit. Diluted blood is drawn, from the patient, inside the fibers of the device while plasma water is removed across the semi-permeable hollow fibers from the blood pathway to the filtrate side. The DHF hemoconcentrators are ethylene oxide sterilized and have a nonpyrogenic fluid path. They are 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 five years real time aging. 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 the "Guidance for the Content of Premarket Notifications for Conventional and High permeability Hemodialyzers" Guidance for industry and CDRH reviewers issued on August 7, 1998 by CDRH and on the EN 1283 "Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits" issued on April 1996 when applicable. The following tests were performed to demonstrate the compliance of the DHF hemoconcentrators with safety and effectiveness requirements: priming volume, pressure drop, ultrafiltration rate, sieving coefficient, mechanical integrity, blood trauma, including measurement of plasma free hemoglobin and index of hemolysis. The results of these tests carried out on the DHF 0.6 and DHF 0.2 Hemoconcentrators aged to 5 years met established specifications. Data collected show that functional and biocompatibility parameters exhibited by the currently marketed Cobe HC 700 Midi and HPH 400 apply to the DHF 0.6 and DHF 0.2 hemoconcentrators.

CONCLUSION:

The new series of DHF hemoconcentrators show comparable or even better performances with respect to their related predicate devices as demonstrated by the *in vitro* test results presented in the submission. 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 the hemoconcentrator is sterile and non-pyrogenic. Therefore the DHF 0.6 and DHF 0.2 hemoconcentrator are substantially equivalent to the predicate devices Cobe HC 700 Midi and Hemocor HPH 400 respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Dideco S.p.A.
c/o Barry Sall, RAC
Senior Regulatory Consultant
PAREXEL International Corp.
195 West Street
WALTHAM MA 02451-1163

Re: K021732
Trade/Device Name: Dideco DHF Hemoconcentrator
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: September 18, 2002
Received: September 19, 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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021732

Device Name: Dideco DHF Hemoconcentrator

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021732