K 052717

OCT 2 0 2005

APPENDIX I

510(K) SUMMARY

510(k) SUMMARY

SUBMITTER:

Dideco S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

Luigi Vecchi
Phone: 011 39 0535 29811
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DATE PREPARED:

September 28, 2005

DEVICE TRADE NAME:

D732 MICRO 27 Ph.I.S.I.O.: Dideco D732 Micro 27 Adult Arterial Filter with 27 micron screen with phosphorylcholine coating (hereafter referred to as D732 MICRO 27 Ph.I.S.I.O.)

COMMON NAME:

Arterial Filter

CLASSIFICATION NAME:

Cardiopulmonary Bypass Arterial Line Blood Filter

UNMODIFIED DEVICE

D732 MICRO 20: Dideco D732 Micro 20 Adult Arterial Filter with 20 micron screen (hereafter referred to as D732 MICRO 20) (K952270).

PREDICATE DEVICE:

D736 Micro 40 Ph.I.S.I.O.: Dideco Micro 40 Ph.I.S.I.O. Newborn-Infant Arterial Filter with 40 micron screen with biocompatible treatment surface (K002493) (hereinafter referred to as the D736 MICRO Ph.I.S.I.O

DEVICE DESCRIPTION:

The D732 MICRO 27 Ph.I.S.I.O. is sterile, non-pyrogenic disposable filter for use in the arterial line of the cardiopulmonary bypass circuit with the flow rate not exceeding 7.0 liters/minute. The D732 MICRO 27 Ph.I.S.I.O. is an Adult Arterial Filter with 27 micron filter screen designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris greater than 27 microns from the arterial line perfusate. The D732 MICRO 27 Ph.I.S.I.O. is a modified version of the currently marketed D732 MICRO 20. The modification

consists of coating all blood contact surfaces with phosphorylcholine additive that improves the blood compatibility of the substrate materials and change of the pleated polyester filter screen pore size from 20 to 27 micron. Other than this change the D 732 MICRO 27 Ph.I.S.I.O. and the D 732 MICRO 20 are identical in design, materials, and manufacturing processes.

INDICATION FOR USE:

The Dideco D732 MICRO 27 Ph.I.S.I.O. with 27 micron screen with phosphorylcholine coating is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filter is used to trap and remove gaseous emboli as well as particulate debris that maybe introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The D732 Micro 27 Ph.I.S.I.O. has the same design features, operating principles and control mechanisms when compared to the D732 predicate devices. The D732 Micro 27 Ph.I.S.I.O. utilize the same materials (with the exception of addition of the phosphorylcholine coating), filtering media with the exception of the different filter pore size (27 micron instead of 20 micron) and the same main blood flow path as the unmodified devices.

The D732 MICRO 27 Ph.I.S.I.O. are identical to the current MICRO Adult series unmodified devices in design, operating principles, control mechanisms and fundamental scientific technology. No change to the intended use has been made as result of the addition of the phosphorylcholine coating to all blood contact surfaces and of the change of the filter screen pore size. Both devices share the identical manufacturing process. The Ph.I.S.I.O. coating solutions used for the D732 MICRO 27 Ph.I.S.I.O. as well as manufacturing process for applying the coating, is identical to that used for the D736 MICRO 40 Ph.I.S.I.O. (K002493) predicate device. There are no differences in packaging type and material between the D732 MICRO 27 Ph.I.S.I.O. and the MICRO undmodified device. The arterial filters are ethylene oxide sterilized and have a nonpyrogenic fluid path. They are for single use only.

NON CLINICAL 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 D736 MICRO 40 Ph.I.S.I.O. (accelerated aging). The devices were aged up to three years and tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity, Sterility, Pyrogenicity and ETO residuals. Package integrity testing was also conducted. The results of the testing met established specifications. As no new materials are used in the D732 MICRO 27 Ph.I.S.I.O. adult arterial filter with respect to the D736 MICRO 40 Ph.I.S.I.O data collected are considered applicable to both MICRO Ph.I.S.I.O filters.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for Industry, dated November 29, 2000. These data demonstrate substantial equivalence with the unmodified devices and show that the devices are compliant with safety and effectiveness requirements. The device was aged up to 3 years and tested for structural integrity, mechanical integrity, blood side pressure drop, filter flow rate capacity, *in vitro* hemolysis/cell depletion and air handling characteristics. For comparative purposes all tests were performed on sterilized aged devices comparing the D732 MICRO 27 Ph.I.S.I.O. vs. the D732 MICRO 20 non aged unmodified device operated at 7.0 LPM when applicable. The results of these tests met established specifications. The modifications being made to the MICRO Ph.I.S.I.O. arterial filter due to the presence of the Ph.I.S.I.O. coating affect the performance of the device in a statistically significant manner; therefore the performance characteristic demonstrated by the D732 MICRO 27 Ph.I.S.I.O. in terms of pressure drop andhemolysis are improved with respect to the D732 unmodified device. There is no statistically significant difference in the air handling characteristics between the D732 MICRO 27 Ph.I.S.I.O and the D732 unmodified device. The filtration efficiency of the D 732 MICRO 27 Ph.I.S.I.O. meets the 80% particles removal requirement as per AAMI Standard.
The results of the study showed that the device characteristics of the D732 MICRO 27 Ph.I.S.I.O. vs. D732 MICRO 20 unmodified device are equivalent.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the D732 MICRO 27 Ph.I.S.I.O. device performs in a manner substantially equivalent to the unmodified device. The presence of the coating is advantageous in terms of reduced pressure drop and hemolysis. Biocompatibility and functional tests demonstrate that its performance is equivalent to the D732 unmodified devices, according to their intended use. Additional testing has demonstrated the effectiveness of production techniques assuring that the adult arterial filters are sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Dideco S.R.L.
c/o Mr. Barry Sall
Parexel International
200 West Street
Waltham, MA 02451

Re: K052717
D732 MICRO 27 Ph.I.S.I.O.: Dideco D732 Micro 27 Adult Arterial Filter with 27 micron screen with phosphorylcholine coating
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II (Two)
Product Code: DTM
Dated: September 28, 2005
Received: September 29, 2005

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 (240) 276-0120. 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/industry/support/index.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: D732 MICRO 27 Ph.I.S.I.O., Dideco D732 Micro 27 Adult Arterial Filter with 27 micron screen with phosphorylcholine coating

Indications for Use:

The Dideco D732 MICRO 27 Ph.I.S.I.O. with 27 micron screen with phosphorylcholine coating is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filter it is used to trap and remove gaseous emboli as well as particulate debris that maybe introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052717