K041061

MAY - 6 2004

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:

April 23, 2004

DEVICE TRADE NAME:

D731 MICRO 20: Dideco D731 Micro 20 Pediatric Arterial Filter with 20 micron screen (hereafter referred to as D731 MICRO 20) and
D733 MICRO 40: Dideco D733 MICRO 40 Pediatric Arterial Filter with 40 micron screen (hereafter referred to as D733 MICRO 40)

COMMON NAME:

Arterial Filter

CLASSIFICATION NAME:

Cardiopulmonary Bypass Arterial Line Blood Filter

PREDICATE DEVICES:

D731 MICRO 20: Dideco D731 Micro 20 Pediatric Arterial Filter with 20 micron screen and D733 MICRO 40: Dideco D733 MICRO 40 Pediatric Arterial Filter with 40 micron screen (hereafter referred to as D731 and D733 respectively) (K945198).

DEVICE DESCRIPTION:

The D731 MICRO 20 and D733 MICRO 40 are sterile, non-pyrogenic disposable filters for use in arterial line of the cardiopulmonary bypass circuit with the flow rate not exceeding 5.0 liters/minute. The D731 MICRO 20 and D733 MICRO 40 are Pediatric Arterial Filters with 20 and 40 micron filter screens designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris greater than 20 and 40 microns respectively from the arterial line perfusate. The maximum blood flow rate has been increased to 5.0 liters/minute.

INDICATION FOR USE:

The Dideco D731 MICRO 20 with 20 micron screen and the Dideco D733 MICRO 40 with 40 micron screen are recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filters are 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 D731 MICRO 20 and the D733 MICRO 40 have the same design features, operating principles and control mechanisms when compared to the D731/D733 predicate devices. The D731 MICRO 20 and the D733 MICRO 40 utilize the same materials, filtering media with the same filter pore size (20 and 40 micron respectively) and the same main blood flow path as the predicate devices.

The D731 MICRO 20 and of the D733 MICRO 40 are, with the exception of the increase of the maximum blood flow rate up to 5.0 LPM, identical to the current MICRO Pediatric series predicate devices. No change of the intended use has been made as result of the extension of the maximum blood flow rate up to 5.0 LPM for both the D731 MICRO 20 and D733 MICRO 40. Both devices share the identical manufacturing process. The arterial filters are ethylene oxide sterilized and have a nonpyrogenic fluid path. They are 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 D731 MICRO 20 and of the D733 MICRO 40 (accelerated aging). The devices were aged up to five 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. No new materials are used in the Pediatric arterial filter as compared to the predicate devices. This 510(k) cross references biocompatibility data previously submitted in D731 MICRO 20 Dideco Pediatric Arterial Filter with 20 micron screen and D733 MICRO 40 Dideco Pediatric Arterial Filter with 40 micron screen 510(k) (K945198).

***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 predicate devices and show that the devices are compliant with safety and effectiveness requirements. The device was aged up to 5 years and tested for structural integrity, mechanical integrity, blood side pressure drop, filter flow rate capacity, *in vitro* hemolysis/cell depletion, filtration efficiency and air handling characteristics. For comparative purposes all tests were performed on sterilized aged devices comparing the D731 MICRO 20 operated at 3.0 LPM vs. the D733 predicate device operated at 5.0 LPM and D731 MICRO 40 operated at 3.0 LPM vs. D733 predicate device operated at 5.0 LPM when applicable. The results of these tests met established specifications.

The results of the study showed that the device characteristics of the D731 MICRO 20 vs. D731 predicate device and D733 MICRO 40 vs. D733 predicate device were comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the D731 MICRO 20 and D733 MICRO devices perform in a manner substantially equivalent to the predicate devices. Biocompatibility and functional tests demonstrate that their performance is equivalent to the D731 and D733 predicate devices, according to their intended use. Additional testing has demonstrated the effectiveness of production techniques assuring that the newborn-infant 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

MAY - 6 2004

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

Re: K041061
D731 Micro 20 and D733 Micro 40 Pediatric Arterial Filters
Regulation Number: 21 CFR 870.4260
Regulation Name: Filter, Blood, Cardiopulmonary, Arterial Line
Regulatory Class: Class II (two)
Product Code: DTM
Dated: April 23, 2004
Received: April 23, 2004

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. 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) you may obtain. 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): K041061

Device Name: D731 MICRO 20, Dideco D731 Micro 20 Pediatric Arterial Filter with 20 micron screen and for the D733 MICRO 40, Dideco D733 Micro 40 Pediatric Arterial Filter with 40 micron screen

Indications for Use:

The Dideco D731 MICRO 20 with 20 micron screen and the Dideco D733 MICRO 40 with 40 micron screen are recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filters are 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 K041061