

KG51232

Dideco S.r.l.
D731/733 MICRO Ph.I.S.I.O. Pediatric Arterial Filters

Special 510(k): Device Modification
May 12, 2005

APPENDIX I

MAY 20 2005

510(K) SUMMARY

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DATE PREPARED: May 12, 2005

DEVICE TRADE NAME: D731 MICRO 20 Ph.I.S.I.O.: Dideco D731 Micro 20 Pediatric Arterial Filter with 20 micron screen with phosphorylcholine coating (hereafter referred to as D731 MICRO 20 Ph.I.S.I.O.) and D733 MICRO 40 Ph.I.S.I.O.: Dideco D733 MICRO 40 Pediatric Arterial Filter with 40 micron screen with phopshorilcoline coating (hereafter referred to as D733 MICRO 40 Ph.I.S.I.O)

COMMON NAME: Arterial Filter

CLASSIFICATION NAME: Cardiopulmonary Bypass Arterial Line Blood Filter

UNMODIFIED 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 and K041061).

PREDICATE DEVICES: D736 MICRO 40 Ph.I.S.I.O.: Dideco D736 Micro 40 Ph.I.S.I.O. Newborn/Infant Arterial Filter with 40 micron screen with biocompatible treatment surface (K002493) (hereafter referred to as D736 MICRO Ph.I.S.I.O.

DEVICE DESCRIPTION:

The D731 MICRO 20 Ph.I.S.I.O. and D733 MICRO 40 Ph.I.S.I.O. are sterile, non-pyrogenic disposable filters for use in the arterial line of the cardiopulmonary bypass circuit with the flow rate not exceeding 5.0 liters/minute. The D731 MICRO 20 Ph.I.S.I.O. and D733 MICRO 40 Ph.I.S.I.O. 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 D731 MICRO 20 Ph.I.S.I.O. and D733 MICRO 40 Ph.I.S.I.O. are a modified version of the currently marketed D731/D733 MICRO. The modification consists of coating all blood contact surfaces with phosphorylcholine additive that improves the blood compatibility of the substrate materials. Other than this change the D 731/D733 MICRO Ph.I.S.I.O. and the D 731/D733 MICRO are identical in design, materials, and manufacturing processes.

INDICATION FOR USE:

The Dideco D731 MICRO 20 Ph.I.S.I.O. with 20 micron screen with phosphorylcholine coating and the Dideco D733 MICRO 40 Ph.I.S.I.O. with 40 micron screen with phosphorylcholine coating 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 Ph.I.S.I.O. and the D733 MICRO 40 Ph.I.S.I.O. have the same design features, operating principles and control mechanisms when compared to the D731/D733 predicate devices. The D731 Micro 20 Ph.I.S.I.O. and the D733 MICRO 40 Ph.I.S.I.O. utilize the same materials (with the exception of addition of the phosphorylcholine coating), filtering media with the same filter pore size (20 and 40 micron respectively) and the same main blood flow path as the unmodified devices.

The D731 MICRO 20 Ph.I.S.I.O. and of the D733 MICRO 40 Ph.I.S.I.O. are identical to the current MICRO Pediatric 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. Both devices share the identical manufacturing process. The Ph.I.S.I.O. coating solutions used for the D731 MICRO 20 Ph.I.S.I.O. and the D733 MICRO 40 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 D731/D733 MICRO Ph.I.S.I.O. and the MICRO unmodified devices. 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 D 733 MICRO 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 D731 MICRO 20 Ph.I.S.I.O. pediatric arterial filter with respect to the D733 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. For comparative purposes all tests were performed on sterilized aged devices comparing the D731 MICRO 20 Ph.I.S.I.O. vs. the D733 non aged unmodified device and D731 MICRO 40 Ph.I.S.I.O. vs. D733 non aged unmodified device operated at 5.0 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 do not affect the performance of the device; therefore the filtration efficiency and air handling characteristics exhibited by the D731/D733 MICRO unmodified device apply also to the MICRO Ph.I.S.I.O. arterial filters.

The results of the study showed that the device characteristics of the D731 MICRO 20 Ph.I.S.I.O. vs. D731 unmodified device and D733 MICRO 40 Ph.I.S.I.O. vs. D733 unmodified device were comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the D731 MICRO 20 Ph.I.S.I.O. and D733 MICRO Ph.I.S.I.O. devices perform in a manner substantially equivalent to the unmodified devices. Biocompatibility and functional tests demonstrate that their performance is equivalent to the D731 and D733 unmodified 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2005

Dideco S.R.L.
c/o Mr. Barry Sall
Senior Regulatory Consultant
Parexel International
195 West Street
Waltham, MA 02451-1163

Re: K051232
D731 Micro 20 Ph.I.S.I.O. Pediatric Arterial Filter, D733M
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Blood Filter
Regulatory Class: Class II (Two)
Product Code: DTM
Dated: May 12, 2005
Received: May 13, 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.

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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" (21 CFR 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,



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): K051232

Device Name: D731 MICRO 20 Ph.I.S.I.O., Dideco D731 Micro 20 Pediatric Arterial Filter with 20 micron screen with phosphorylcholine coating and for the D733 MICRO 40 Ph.I.S.I.O., Dideco D733 Micro 40 Pediatric Arterial Filter with 40 micron screen with phosphorylcholine coating

Indications for Use:

The Dideco D731 MICRO 20 Ph.I.S.I.O., with 20 micron screen with phosphorylcholine coating and the Dideco D733 MICRO 40 Ph.I.S.I.O., with 40 micron screen with phosphorylcholine coating 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)

Over-the-Counter Use _____
AND/OR (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)

K051232 B. Gammone
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number 051232