Medtronic

JUL - 3 2007

510(k) Summary

K071253

Date Prepared: April 25, 2007

Submitter: Medtronic
7611 Northland Drive
Brooklyn Park, MN 55428

Contact Person: Jessica Sixberry
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Device Name and Classification:

Trade Name: Affinity® Pediatric Arterial Filter
Common Name: Cardiopulmonary bypass arterial line blood filter
Regulation Number: 21 CFR 870.4260
Product Code: DTM
Classification: Class II

Predicate Devices

Terumo Capiox Arterial Filter, AF02, Pediatric (K943917)
Medtronic Affinity® Arterial Filter (K952532)
Medtronic Affinity® Arterial Filter, Carmeda® Coated (K000379)

Device Description

The AFFINITY® Pediatric Arterial Filters are single-use, sterile, nonpyrogenic devices designed to filter microemboli greater than the specified micron size from the circuit for periods up to six hours during cardiopulmonary bypass surgery. These devices are available both in an uncoated and a Carmeda coated option. The Carmeda coating is a BioActive Surface that is non-leaching and provides a thromboresistant blood contact surface.

Indications for Use

The AFFINITY® Pediatric Arterial Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Comparison to Predicate Devices

The AFFINITY® Pediatric Arterial Filter has the same technological characteristics when compared to the existing devices. This device utilizes the design features and materials of the adult Medtronic AFFINITY® Arterial Filter but meets the performance characteristics of the Terumo Pediatric arterial filter CAPIOX AF02.

- Intended Use: The AFFINITY® Pediatric Arterial Filter has the same intended use as the Medtronic AFFINITY® Arterial Filter.
- Principles of Operation and Technology: The AFFINITY® Pediatric Arterial Filter uses the same technologies in operation of the of the AFFINITY® Arterial Filter. The AFFINITY® Pediatric Arterial Filter is a miniaturized version of the AFFINITY® Arterial Filter. Air removal and filtration are accomplished in the same manner. Both filters are also made from the same materials.
- Performance: The AFFINITY® Pediatric Arterial Filter was compared to the Terumo AF02 for performance characteristics as this is also a pediatric filter. The comparisons demonstrated that these were substantially equivalent in performance.

Summary of Performance Data

Functional testing was used to establish the performance characteristics of the modifications of this device from previously marketed devices. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Filtration Efficiency
- Air Handling Capabilities
- Effect of Device on Cellular Blood Components
- Pressure Drop
- Structural Integrity
- Priming Volume

Conclusion

Medtronic has demonstrated that the AFFINITY® Pediatric Arterial Filter is substantially equivalent to the predicate devices based upon design, test results, and indications for use. Any noted differences do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2007

Medtronic, Inc.
c/o Ms. Jessica Sixberry
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive
Brooklyn Park, MN 55428

Re: K071253
Affinity Pediatric Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: Class II
Product Code: DTM
Dated: April 25, 2007
Received: May 4, 2007

Dear Ms. Sixberry:

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) 2760120. 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 (240) 276-3150 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): K071253

Device Name: AFFINITY® Pediatric Arterial Blood Filter, also available with CARMEDA® Bioactive Surface

Indications for Use: AFFINITY® Pediatric Arterial Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley Boam for BDZ
(Division Sign-Off)
Division of Cardiovascular Devices

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