NOV 2 2 2005

K052524

510(k) Summary

Date Prepared: September 7, 2005

Submitter:

Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:

Bruce Backlund
Senior Regulatory Affairs Specialist

Phone: (763)-391-9183
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Device Name and Classification:

Trade Name: Bio-Medicus Multi-Stage Venous Femoral Percutaneous Kit

Common Name: Percutaneous Cannula and Introducer Set

Classification: Class II

Predicate Devices: Bio-Medicus Femoral Cannula and Introducer K884129

Device Description

The Biomedicus Femoral Cannula and Introducer Set include the new Bio-Medicus Femoral Venous Cannula and Introducer. The Cannula are one piece, wire wound bodies with basket type holes. Insertion depth marks aid in positioning the Cannula. All are supplied sterile, and non-pyrogenic and are single use.

This new Biomedicus Femoral Venous Cannula and Introducer Set consists of a longer flexible cannula with multiple side holes, a longer introducer, an improved introducer to cannula tip transition and 3/8" barbed connector.

The cannulae are available in 19 Fr, 21 Fr and 25 Fr sizes.

The Cannula are intended to be used to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal equipment. The Cannula Introducer is intended to facilitate proper insertion and placement of the appropriate sized Cannula within the vessel for cardiopulmonary bypass.

The overall product length is approximately 30.125 inches. The device is sterile, non-pyrogenic and disposable, and is intended for short-term single use.

The product will be available in both Carmeda coated and uncoated versions.

Indications for Use

The percutaneous cannula is for use by trained physicians only, to cannulate vessels, perfuse vessels or organs in a patient for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed.

This product is intended for use up to six hours or less.

Comparison to Predicate Device

The predicate device 510(k) K884129 was cleared on December 21, 1988. This 510(k) was for various sizes and shapes of Cannula.

This Cannula was indicated as intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory Extracorporeal equipment.

The Cannula Introducer is intended to facilitate proper insertion and placement of the appropriate sized Cannula within the vessel for cardiopulmonary bypass.

A copy of the original IFU as provided in the 510(k) is included in Appendix A.

Summary of Performance Data

Validation testing was used to establish the performance characteristic of the modifications of this device from the previously marketed device.

Conclusion

Medtronic Perfusion Systems has demonstrated that the Bio-Medicus Femoral Venous Cannula and Introducer is substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medtronic Perfusion Systems
c/o Mr. Bruce Backlund
Senior Regulatory Affairs Specialist
7611 Northland Drive N
Brooklyn Park, MN 55428

Re: K052524
Bio-Medicus Multi-Stage Venous Femoral Percutaneous Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (Two)
Product Code: DWF
Dated: October 28, 2005
Received: October 31, 2005

Dear Mr. Backlund:

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,

Donna R. Vachuska

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052524

Device Name: Bio-Medicus Multistage Venous Femoral Percutaneous Kit

Indications for Use:

The percutaneous cannula is for use by trained physicians only, to cannulate vessels, perfuse vessels or organs in a patient for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed.

This product is intended for use up to six hours or less

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052524

(Posted November 13, 2003)