K961103

Section 5 - 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter

Haemonetics Corporation
400 Wood Road
Braintree, MA. 02184-9114

MAY 17 2006

Contact

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Device Name

Proprietary Name:	Haemonetics® 40µ RBC Filter Bag
Common Name:	Blood Transfusion Microfilter
Classification Name:	Intravascular Administration Set (component)

Predicate Device

The predicate device is the **Filter Bag, BF-40, of the Harvest® BloodStream® Recovery System.** The Harvest Filter Bag device was cleared in K942844 on 4/26/96. Haemonetics acquired this product line from Harvest in August 2004.

Description

The Haemonetics 40µ RBC Filter Bag is described as a blood transfusion microfilter with FDA Product Code CAK in the FDA Guidance Document for Intravascular Administration Sets 510(k)s dated April 15, 2005. It is defined as a Class II medical device in 21 CFR 880.5440 and is included as a component for an Intravascular Administration Set.

K061193

The Haemonetics 40µ RBC Filter Bag is intended for use for perioperative autologous transfusion to hold washed red blood cells from a Haemonetics cell salvage device and filter the RBCs for microaggregates greater than 40 microns (40µ). It is intended to eliminate the need for a discrete 40 micron filter often used to filter autotransfusion blood prior to reinfusion. The 40µ RBC Filter Bag has a similar intended use as the predicate device. It is designed to be used by trained hospital personnel under the direction of a physician. Therefore, it is to be used as a prescription medical device, which is indicated by the symbol on the labeling as "Rx Only".

Indications for Use

The Haemonetics 40µ RBC Filter Bag is intended for use for perioperative autologous transfusion to hold washed red blood cells from a Haemonetics cell salvage device and filter the RBCs for microaggregates greater than 40 microns. It is intended to eliminate the need for a discrete 40 micron filter often used to filter autotransfusion blood prior to reinfusion.

Performance Testing – Bench

Haemonetics has conducted testing to verify the safety and performance of the 40µ RBC Filter Bag. A detailed list with summaries of testing is provided with the test protocols and reports.

Substantial Equivalence

The substantial equivalence of the 40µ RBC Filter Bag is supported by its similarities in intended use and performance characteristics, as compared to the currently marketed Harvest BloodStream Recovery System, Filter Bag, BF-40. They are similar in design, materials of construction, and manufacturing processes. Verification and validation testing has been completed on the 40µ RBC Filter Bag and provides valid scientific evidence to demonstrate the devices are substantially equivalent in accordance with applicable standards referenced in the reports.

Gabriel J. Muraca, Jr.
Regulatory Affairs Project Manager
Haemonetics Corporation

Date: March 8, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Haemonetics Corporation
C/O Mr. Tamas Borsai
Responsible Third Party Official
TUV Rheinland of North America, Incorporated
1279 Quarry Lane, Suite A
Pleasanton, California 94566

Re: K061103
Trade/Device Name: Haemonetics® 40µ RBC Filter Bag
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: CAK
Dated: May 1, 2006
Received: May 2, 2006

Dear Mr. Borsai:

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) 276-0115. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K061403

Device Name:

Haemonetics® 40µ RBC Filter Bag

Indications for Use:

The Haemonetics 40µ RBC Filter Bag is intended for use for perioperative autologous transfusion to hold washed red blood cells from a Haemonetics cell salvage device and filter the RBCs for microaggregates greater than 40 microns. It is intended to eliminate the need for a discrete 40 micron filter often used to filter autotransfusion blood prior to reinfusion.

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K061403

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)