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**Fresenius Combilines with Access Flow Reversing Connector**
**510(k) Premarket Notification**

# 510K Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the Fresenius Combiset with Access Flow Reversing Connector.

Company: Fresenius Medical Care North America
95 Hayden Ave.
Lexington, MA 02420
Date: July 29, 2002
Trade Name: Fresenius Access Flow Reversing Connector
Common Name: Blood Tubing Accessories
Classification Name and Reference: 21 CFR §876.5820 Blood Tubing Set, with or without Anti-Regurgitation Valve – Class II
Device Product Code and Panel Code: KOC, 78
Predicate Device: Medisystems Blood Tubing Set Accessories (Revers⌐™); K994306, SE 3/20/2000

Description:
The Fresenius Access Flow Reversing Connector is designed to be used during hemodialysis when an access flow measurement is required. The AFRC facilitates the test procedure by eliminating the need to disconnect the arterial and venous lines and reconnecting them to facilitate the switch in flow direction. The device contains a valve that allows reverse blood flow to and from vascular access sites. The device is manually operated and turns 180° to reverse the blood flow communication. The Fresenius Access Flow Reversing Connector will be available as both a standalone and as a component in the Combilines Hemodialysis bloodline tubing sets.

Intended Use:
The Fresesnius Access Flow Reversing Connector (AFRC) is for use during hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices during hemodialysis in order to obtain an access flow measurement.

The AFRC facilitates the test procedure by eliminating the need to disconnect bloodlines during the test procedure.

It may be used in conjunction with access devices, such as; the Fresenius Online Clearance Monitor™, the CritLine® from HemaMetrics, or the HD01 Hemodialysis Monitor from Transonic Systems when flow reversal is required.

Safety and Performance:
The intended use, technological characteristics, design features, and material are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the Fresenius Access Flow Reversing Connector is supported by the substantial equivalence information, materials data, device description, and performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2002

Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K022536
Trade/Device Name: Fresenius Access Flow Reversing Connector
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KOC
Dated: July 30, 2002
Received: August 1, 2002

Dear Mr. Eilinsfeld:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21 CFR Part 807.97). 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

# Indications for Use Statement

**Device Name:**

**Fresenius Access Flow Reversing Connector**

**Indications for Use:**

The Fresenius Access Flow Reversing Connector (AFRC) is for use during hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices during hemodialysis in order to obtain an access flow measurement.

The AFRC facilitates the test procedure by eliminating the need to disconnect bloodlines during the test procedure.

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022536

*Prescription Use* ✓

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)