K012242
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AUG 1 6 2001

Fresenius Hemodialysis Single Use Arterial Bloodline Sets with Alternate Pump Segment Material "Special" 510(k) Premarket Notification

Section II: General Device Summary

Proprietary Name:	Fresenius Hemodialysis Single Use Arterial Bloodline Sets
Common Name:	Blood Tubing Set, with or without Anti-regurgitation Valve
Product Code/Classification Panel:	78FJK/Gastroenterology-Urology
Classification:	Class II per §876.5820.

Establishment Registration

Manufacturing Facility Address:

Erika de Reynosa, S.A. de C.V.
Brecha E-99
Parque Industrial
Reynosa, Mexico
C.D. Reynosa, Tamps
FDA Establishment Registration Number: 8030665

Sterilization Site:

Cosmed of Texas
1175 Isuzu Parkway
Grand Prairie, TX 75050
FDA Establishment Registration Number: 1650907

Submitter Information

Submitter's Name and Address:

Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420
FDA Establishment Registration Number: 1225714

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Section II: General Device Summary

Contact Information:

Arthur E. Eilinsfeld, Director of Regulatory Affairs
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Alternate Contact:
Lorraine Calzetta Patrovic ,Senior Regulatory Affairs Specialist
Telephone: (781) 402-9785
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Summary of Safety and Effectiveness

The 510(k) Summary of Safety and Effectiveness is provided in **Appendix 1- Summary of Safety and Effectiveness**.

Performance Standards

No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act for Blood Tubing Sets with and without Anti-regurgitation Valves.

- **Compliance with ANSI/AAMI RD17-1994**

  The Fresenius Hemodialysis Arterial Blood Tubing Sets have been designed to meet the requirements for Hemodialyzer Blood Tubing as specified in ANSI/AAMI RD17-1994.

Predicate Device

The predicate device for the Fresenius Single use Arterial Bloodline Sets with Alternate Pump Segment Material is:

- Fresenius Hemodialysis Blood Tubing Sets cleared under K971313 (10/27/97)
- Fresenius Combi Sets® cleared under #K962081 (11/01/96) and #K000451 (05/09/00).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2001

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

Re: K012242
Fresenius Single Use Arterial Bloodline Sets with
Alternate Pump Segment Material
Dated: July 13, 2001
Received: July 17, 2001
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJK

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 (s)

Fresenius Hemodialysis Single Use Arterial Bloodline Sets with Alternate Pump Segment Material "Special" 510(k) Premarket Notification

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Indications for Use/Intended Use

The Fresenius Single use Arterial Bloodline Sets are intended for use as the extracorporeal blood circuit during hemodialysis. They are intended for single use only and are indicated for use with both conventional and high flux negative pressure hemodialyzer equipment.

The Indications for Use statement is provided in **Appendix 2- Indications for Use Statement.**

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012242

Prescription Use ✓
(Per 21 CFR 801.109)