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K971313

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SUMMARY OF SAFETY AND EFFICACY

The proposed hemodialysis arterial blood tubing sets raise no new issues of safety or efficacy. Sterilization method and packaging are essentially the same.

The arterial bloodlines are substantially equivalent to legally marketed bloodlines. These bloodlines have been functionally tested and data provided. The blood contact materials of the arterial bloodlines have been tested for biocompatibility and data provided.

The integrity of the bonded connections of the bloodlines have been tested and data provided.

No new claims or indications are made.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1997

Mr. Art Eilinsfeld
Manager, Regulatory Affairs
Fresenius Medical Care North America
Renal Products Technologies
Two Ledgemont Center
95 Hayden Avenue
Lexington, Massachusetts 02173

Re: K971313
Hemodialysis Arterial Blood Tubing Set
Dated: July 25, 1997
Received: August 14, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 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 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 requirement, 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) 594-4613. 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 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Hemodialysis Arterial Blood Tubing Set

Indications For Use:

The Hemodialysis Arterial Blood Tubing Set is intended for use as the extra corporeal blood circuit during hemodialysis. It is intended for single use only. The Hemodialysis Arterial Blood Tubing Set is indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Watling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971313

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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(Optional Format 1-2-96)