K022412

MAR 0 5 2003

510 (k) Summary

Applicant: Fresenius Medical Care North America

Contact: Arthur E. Eilinsfeld
Director, Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Telephone: 781-402-9068
Fax: 781-402-9082

Trade Name: Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector

Common Name: Disposable Connector and Tubing Set for Solution Delivery during Peritoneal Dialysis

Classification Name: Peritoneal Dialysis System and Accessories per 21CFR 876.5630

Equivalence Predicate: CAPD Safe-Lock™ Transfer Sets with Pre-filled Connector

Device Description: The Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector consists of a circular housing designed with three, evenly spaced, outlet ports. Individual ports specifically provide for attachment either to the patient, to the peritoneal dialysis solution, or to a drain bag. The outlet port plugs allow the start or stop of solution flow; and prior to use the outlet port for the patient connection is covered with a cap.

A knob is turned to different positions to initiate the various treatment steps of the peritoneal dialysis procedure.

Statement of Intended Use: The Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector are disposable devices for single use. The areas under protective guards and the fluid pathway are sterile and non-pyrogenic. The devices continue to be restricted to the sale by or on the order of a physician.

510 (k) Summary

Statement of Indications for Use: It is indicated for use in patients with end-stage acute and chronic renal disease.

Summary of Technological Differences: In general, the design and materials of the subject devices are the same as the Fresenius predicate devices. The materials have been tested to ISO10993 and are shown not to raise any different issues regarding safety and effectiveness. A hazard analysis determination indicates that the design differences do not impact the safety or effectiveness of the device; and that the differences are not critical to the intended therapeutic use of the device.

Clinical Data: Not Applicable

Conclusions: Components of the proposed devices have met the ISO 10993-1 biological requirements for safety screening of materials in indirect contact for greater than 30 days. The sets are tested to a Limulus Amebocyte Lysate (LAL) specification of 0.01 EU/mL. Sets are sterilized by a method determined and verified to assure an SAL of $\geq 10^{-6}$. Functional and physical testing is performed prior to product release.

Arthur E. Eilinsfeld
Director, Fresenius Regulatory Affairs

7/15/02
Date

K022412
Premarket Notification 510 (k) Number

AEE:dmk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 5 2003

Mr. Arthur E. Eilinsfeld
Director, Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420-9192

Re: K022412
Trade/Device Name: Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 KDJ
Dated: December 3, 2002
Received: December 5, 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

Indications for Use Statement

Device Name:

Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector

Indications for Use:

The Fresenius CAPD stay•safe® Disposable Administration Sets with stay•safe® Connector is indicated for use in end stage acute and chronic renal disease.

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022412