SEP 2 4 2004

K041792
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Fresenius STAYSAFE Patient Connectors
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 STAYSAFE Patient Connectors.

Company:	Fresenius Medical Care North America 95 Hayden Ave. Lexington, MA 02420
Date:	July 1, 2004
Contact Person:	Arthur Eilinsfeld
Trade Name:	Fresenius STAYSAFE Patient Connectors
Common Name:	Disposable Peritoneal Dialysis Tubing Sets and Accessories
Classification Name and Reference:	21 CFR §876.5630 Set, Administration, for Peritoneal Dialysis, Disposable – Class II
Device Product Code and Panel Code:	78/KDJ/Gastroenterology-Urology
Predicate Device(s):	Fresenius AMP 80/2 Pediatric Cycler System (now Marketed under ECO™ Peritoneal Dialysis 4 Lead Prefilled Set with Snap Disconnect) (#K811986 - SE 08/31/81); Fresenius CAPD StaySafe Disposable Administration Sets with StaySafe Connector (#K022412 – SE 03/05/03); Fresenius AMP 80/2 Pediatric Cycler System (now Marketed under ECO™ Peritoneal Dialysis 4 Lead Prefilled Set with Snap Disconnect) (#K811986 - SE 08/31/81); Fresenius CAPD Safelock Transfer Set (#K904806 - SE 01/11/91); Closed Disconnect System (#K900106 SE – 07/16/90); submitted under Delmed, now owned by Fresenius Medical Care.

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510K Summary

DEVICE INFORMATION:

A. DESCRIPTION
The Fresenius StaySafe Patient Connectors are designed for use during cycler assisted peritoneal dialysis. The device incorporates a pin and push button/plunger mechanism that provides a closed system after patient disconnection. The pin engages the patient's catheter during a PAUSE or at then end of the treatment. The device also has several accessories associated with its use: StaySafe adaptors. Multiple tubing sets, and extension sets. The device is provided sterile and is for single use only.

B. INTENDED USE
The Fresenius StaySafe Patient Connectors are intended for use with a peritoneal cycler for drainage and infusion of PD solution during peritoneal dialysis exchanges. The Fresenius StaySafe Patient Connectors are indicated acute and chronic peritoneal dialysis.

C. SUBSTANCIAL EQUIVALENCE INFORMATION
The indications for use, technological characteristics, design features, and materials are identical to the predicate devices. The STAYSAFE Patient Connectors are substantially equivalent to the predicate devices supported by the information, materials data, device description, and performance testing submitted and/or described within this 510K.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2004

Ms. Nichole Riek
Regulatory Affairs Supervisor
Fresenius Medical Care - North America
Dialysis Products Division
95 Hayden Avenue
LEXINGTON MA 02420-9192

Re: K041792
Trade/Device Name: STAYSAFE Patient Connectors
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 KDJ
Dated: July 1, 2004
Received: July 2, 2004

Dear Ms. Riek:

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 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 one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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

K041792

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius STAYSAFE Patient Connectors

Indications for Use:

The Fresenius StaySafe Patient Connectors are intended for use with a peritoneal cycler for drainage and infusion of PD solution during a peritoneal dialysis exchanges. The Fresenius StaySafe Patient Connectors are indicated for use in acute and chronic peritoneal dialysis.

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)

Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041792