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K043363

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Fresenius Liberty Cycler and Disposable Cycler Set
510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9635
Contact Person:	Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation:	3 December 2004

B. Device Name:

Trade Name:	Fresenius Liberty Cycler and Disposable Cycler Set
Common/Usual Name:	Peritoneal Dialysis Cycler
Classification Name:	System, Peritoneal, Automatic Delivery

C. Predicate Device Name:

The predicate devices for the Fresenius Liberty Cycler are the following:

- Fresenius 90/2 Cycler - #K902149 (10/30/90);
- Baxter HomeChoice Pro – #K012988 (12/5/01) and #K923065 (3/4/94);
- Fresenius PD^{+} IQcard Cycler - #K002892 (4/5/01).

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Summary of Safety and Effectiveness

D. Device Description/Indications for Use:

The intended use for the Liberty Cycler is identical to that for the Fresenius PD+ IQcard Cycler and is as follows:

Intended Use

The Liberty Cycler is indicated for acute and chronic peritoneal dialysis.

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. **Is the product a device?**

   YES - The Fresenius Liberty Cycler is a device pursuant to 21 CFR §201 [321] (h).

2. **Does the new device have the same intended use?**

   YES – The intended use for the Liberty Cycler is identical to that for the Fresenius PD+ IQcard Cycler and is as follows:

   Intended Use

   The Liberty Cycler is indicated for acute and chronic peritoneal dialysis.

3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

   NO –The Liberty Cycler is the first model in the next generation of Fresenius peritoneal dialysis cyclers. It incorporates features found on other Fresenius cyclers and also utilizes a cassette design similar to the cassette for Baxter HomeChoice Pro. The features included in the Liberty Cycler are equivalent to those present on other commercially available peritoneal dialysis cyclers and raise no new types of safety or effectiveness questions.

Summary of Safety and Effectiveness

4. **Does descriptive or performance information demonstrate equivalence?**

   YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Liberty Cycler and demonstrates that it is substantially equivalent to other commercially available cyclers.

F. Safety Summary

The Fresenius Liberty Cycler Functional and Software validation and release testing rigorously tested the features of the cycler. The results of this testing indicate that the Liberty Cycler is safe and effective for its intended use. In addition, functional testing and biocompatibility testing of the Liberty Cycler Set indicate that the cycler sets are safe and effective for their intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, extensive training is provided to patients that use the Liberty Cycler. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Ms. Nichole Riek
Regulatory Affairs Supervisor
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K043363
Trade/Device Name: Fresenius Liberty Cycler and Disposable Cycler Set
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: March 15, 2005
Received: March 16, 2005

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

K043363

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius Liberty Cycler and Disposable Cycler Set

Indications for Use:

The Fresenius Liberty Cycler is intended for 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 ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043363

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