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CONFIDENTIAL



## Fresenius Medical Care

### Fresenius Sterile Stay Safe® Cap 510(k) Summary

DEC 29 2008

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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: 920 Winter Street  
Waltham, MA 02451  
  
Phone: 1-781-699-4475  
Fax: (781) 699-9635  
Contact Person: Janet C. Kay, RAC, Director of Regulatory Affairs  
Date of Preparation: 25 November, 2008

#### B. Device Name:

Trade Name: Fresenius Sterile Stay Safe® Cap  
Common/Usual Name: Set, Administration, for Peritoneal Dialysis,  
Disposable  
Classification: Class II 876.5630  
ProductCode/  
Classification Panel 78KDJ/Gastroenterology-Urology

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#### **Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000

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#### C. Predicate Device Name:

The Fresenius Sterile Stay Safe® Cap is a modified version of the Fresenius Stay Safe Cap was cleared under the following premarket notifications:

Fresenius Stay Safe® Cap

- #K921818 (3/28/94);

#### D. Indications for Use/Intended Use:

The Indications for Use/Intended Use for the Fresenius Sterile Stay Safe® Cap is equivalent to that for the Fresenius Stay Safe Cap and is as follows:

**Indications for Use**

*Fresenius Sterile Stay Safe® Cap is intended to be used for closure of the stay safe peritoneal dialysis connectology system*

#### E. Substantial Equivalence:

1. Is the product a device?

YES - The Fresenius Sterile Stay Safe® cap is a device pursuant to 21 CFR §201 [321] (h).



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

**YES** – The intended use for the Fresenius Sterile Stay Safe® Cap is equivalent to that for the Fresenius Stay Safe Cap and is as follows:

**Fresenius Sterile Stay Safe® Cap - Intended Use**

*Fresenius Sterile Stay Safe® Cap is intended to be used for closure of the stay safe peritoneal dialysis connectology system*

**Fresenius Stay Safe® Cap - Intended Use**

*Fresenius Sterile Stay Safe® Cap is intended to be used for closure of the stay safe peritoneal dialysis connectology system*

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

**NO** – The Fresenius Sterile Stay Safe® Cap is a modified version of the Fresenius Stay Safe® Cap. The modification is the cap is now sterile. The technological characteristics of the Fresenius Sterile Stay Safe® Cap are equivalent to those of the Fresenius Stay Safe® Cap and raise no new types of safety or effectiveness questions.

**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 Fresenius Sterile Stay Safe® Cap and demonstrates that it is substantially equivalent to the Fresenius Stay Safe® Cap.

**F. Safety Summary**

The Fresenius Sterile Stay Safe® Cap is substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius Stay Safe Cap. In addition, testing of the Fresenius Sterile Stay Safe Cap indicates that the sterile cap is safe and effective for its intended use.

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Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 29 2008

Janet C. Kay, RAC  
Director of Regulatory Affairs  
Fresenius Medical Care North America  
920 Winter Street  
WALTHAM MA 02451

Re: K083542  
Trade/Device Name: Fresenius Sterile Stay Safe® Cap  
Regulation Number: 21 CFR §876.5630  
Regulation Name: Peritoneal dialysis system and accessories  
Regulatory Class: II  
Product Code: KDJ  
Dated: November 25, 2008  
Received: November 28, 2008

Dear Ms. Kay:

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 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

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# Fresenius Medical Care

## Fresenius Sterile Stay Safe® Cap "Special" 510(k) Premarket Notification

**Device Name:**

Fresenius Sterile Stay Safe® Cap

**Indications for Use:**

The Fresenius Sterile Stay Safe® Cap is intended to be used for closure of the stay safe peritoneal dialysis connectology system.

**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

**Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000

*Colin Fohant (acting)*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K083542