



Food and Drug Administration
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Silver Spring, MD 20993-0002

October 29, 2015

Baxter Healthcare Corporation
John Lamela
Specialist, Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073

Re: K152675
Trade/Device Name: MiniCap Extended Life PD Transfer Sets, Locking Titanium Adapter for Peritoneal Dialysis Catheter and Locking Cap for Peritoneal Dialysis Catheter Adapter
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: KDJ
Dated: September 17, 2015
Received: September 18, 2015

Dear John Lamela,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152675

Device Name

MiniCap Extended Life PD Transfer Sets

Indications for Use (Describe)

This set is used during Peritoneal Dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K152675

Device Name

Locking Titanium Adapter for Peritoneal Dialysis Catheter and
Locking Cap for Peritoneal Dialysis Catheter Adapter

Indications for Use (Describe)

Titanium Adapter: The Locking Titanium Adapter for Peritoneal Dialysis Catheter is intended to secure the peritoneal catheter tubing to the Baxter transfer set used during Peritoneal Dialysis therapy.

Locking Cap: This device is indicated for use in the treatment of patients receiving peritoneal dialysis therapy, to cap the Locking Titanium Adapter for Peritoneal Dialysis Catheter between Baxter Transfer Set installations.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5. 510(k) Summary

Sept. 17, 2015

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

John Lamela
Specialist, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: 224-270-2850
Fax: 224-270-4119

IDENTIFICATION OF THE DEVICE:

Common Name: Transfer Sets

Trade Name or Proprietary Name: Minicap Extended Life PD Transfer Sets

Classification Panel: 78 Gastroenterology/Urology

Classification: Set, Administration, For Peritoneal Dialysis, Disposable (21 CFR 876.5630)

Class: II

Product Code: KDJ

Table 1. Product Code(s) for Transfer Sets

Code Number	Name
5C4482	MiniCap Extended Life PD Transfer Set with Twist Clamp
5C4483	MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short



PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Extended Life CAPD Transfer Set 5C4444	Baxter Healthcare Corporation	K882498	07/13/1988

DESCRIPTION OF THE DEVICE:

The MiniCap Extended Life PD Transfer Sets are single use, sterile, non-pyrogenic devices for use with Baxter peritoneal dialysis systems. A Transfer Set is connected to a Titanium Adapter that is at the end of an implanted peritoneal catheter. The Transfer Sets stay connected to the patient and allows for the exchange of peritoneal dialysis solution into and out of the peritoneal cavity as prescribed.

INDICATIONS FOR USE:

This set is used during Peritoneal Dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device has equivalent technological characteristics as Baxter’s currently legally marketed Transfer Sets cleared under 510(k) premarket notification K882498 (cleared on July 13, 1988). The intended use, design and function of the proposed devices are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analysis and design verification tests based on the result of the nonclinical tests. All results meet their acceptance criteria, and support that the proposed device is appropriately designed for its intended use.

Performance Data:

The following functional testing was performed to ensure proper design and function of the devices:

- Leak Test – Twist Clamp Closed
- Twist Clamp Torque to Open/Close



- Leak Test – Transfer Set to Patient Connector (HomeChoice Adult Set, HomeChoice Pediatric Set, Twin Bag Set, Ultra Bag Set, Y-Set)
- Patient Connector – Torque On to Transfer Set (HomeChoice Adult Set, HomeChoice Pediatric Set, Twin Bag Set, Ultra Bag Set, Y-Set)
- Patient Connector – Torque Off from Transfer Set
- MiniCap Test – Attachment Torque On/Off to Transfer Set
- Leak Test – MiniCap to Transfer Set
- Flow Test – CAPD Therapy and APD Therapy

Biocompatibility:

Biocompatibility assessment has been conducted on all materials to the category of external communicating devices with tissue bone dentin and indirect blood path contact for permanent duration. The biocompatibility evaluation for these devices was conducted in accordance with ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”, as recognized by the FDA and FDA Blue Book Memorandum #G95-1, “Use of International Standard ISO-10993”. The battery of testing included:

- Cytotoxicity
- Systemic Toxicity (Acute and Sub-chronic)
- Irritation (Intracutaneous Reactivity)
- Sensitization
- Hemocompatibility

CONCLUSION:

The non-clinical data supports the safety of the proposed devices and demonstrates that the proposed devices perform comparably to the predicate device that is currently marketed for the same intended use.



Section 5. 510(k) Summary

Sept. 16, 2015

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

John Lamela
Specialist, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: 224-270-2850
Fax: 224-270-4119

IDENTIFICATION OF THE DEVICE:

Common Name: Titanium Adapter and Locking Cap

Trade Name or Proprietary Name: Locking Titanium Adapter for Peritoneal Dialysis Catheter and Locking Cap for Peritoneal Dialysis Catheter Adapter

Classification Panel: 78 Gastroenterology/Urology

Classification: Set, Administration, For Peritoneal Dialysis, Disposable (21 CFR 876.5630)

Class: II

Product Code: KDJ

Table 1. Product Code(s)

Code Number	Name
5C4129	Locking Titanium Adapter for Peritoneal Dialysis Catheter
5C4169	Locking Cap for Peritoneal Dialysis Catheter Adapter



PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Peritoneal Dialysis Titanium Catheter Adapter and Locking Cap for Titanium Adapter – Product Codes 5C4168 and 5C4169	Baxter Healthcare Corporation	K894783	September 7, 1989

DESCRIPTION OF THE DEVICE:

The Locking Titanium Adapter for Peritoneal Dialysis Catheter (Titanium Adapter) and Locking Cap for Peritoneal Dialysis Catheter (Locking Cap) are single use, sterile, non-pyrogenic devices for use with Baxter peritoneal dialysis systems. The Titanium Adapter is a device that is secured to the end of a peritoneal dialysis catheter and is used to connect the peritoneal dialysis catheter to the Transfer Sets. The Locking Cap is used to cap the end of the Titanium Adapter between Transfer Set installations.

INDICATIONS FOR USE:

Titanium Adapter: The Locking Titanium Adapter for Peritoneal Dialysis Catheter is intended to secure the peritoneal catheter tubing to the Baxter transfer set used during Peritoneal Dialysis therapy.

Locking Cap: This device is indicated for use in the treatment of patients receiving peritoneal dialysis therapy, to cap the Locking Titanium Adapter for Peritoneal Dialysis Catheter between Baxter Transfer Set installations.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices have equivalent technological characteristics as Baxter’s currently legally marketed Titanium Adapter and Locking Cap cleared under 510(k) premarket notification K894783 (cleared on August 7, 1989). The intended use, design and function of the proposed devices are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analysis and design verification tests based on the result of the nonclinical tests. All results meet their acceptance criteria, and support that the proposed device is appropriately designed for its intended use.



Performance Data:

The following functional testing was performed to ensure proper design and function of the devices:

- Titanium Adapter/Patient Catheter Tubing Seal Test
- Tensile Pull Test - Titanium Adapter to Patient Catheter Tubing
- Locking Cap Removal Torque Test
- Locking Cap Torque On Test
- Tensile Strength – Adapter Catheter to Luer End of Titanium Adapter
- Adapter Catheter to Titanium Adapter - Torque On Test
- Adapter Catheter to Titanium Adapter - Torque Off Test
- Leak Test – Adapter Catheter to Titanium Adapter
- Simulation Testing

Biocompatibility:

Biocompatibility assessment has been conducted on all materials to the category of external communicating devices with tissue bone dentin and indirect blood path contact for permanent duration. The biocompatibility evaluation for these devices was conducted in accordance with ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”, as recognized by the FDA and FDA Blue Book Memorandum #G95-1, “Use of International Standard ISO-10993”. The battery of testing included:

- Cytotoxicity
- Systemic Toxicity (Acute and Sub-chronic)
- Irritation (Intracutaneous Reactivity)
- Sensitization
- Hemocompatibility

CONCLUSION:

The non-clinical data supports the safety of the proposed devices and demonstrates that the proposed devices perform comparably to the predicate device that is currently marketed for the same intended use.