



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

October 29, 2015

Baxter Healthcare Corporation  
Tiffany Lin  
Manager, Regulatory Affairs  
32650 N. Wilson Road  
Round Lake, IL 60073

Re: K152129  
Trade/Device Name: FlexiCap Disconnect Cap with Povidone-Iodine Solution,  
MiniCap with Povidone-Iodine Solution  
Regulation Number: 21 CFR§ 876.5630  
Regulation Name: Peritoneal dialysis system and accessories  
Regulatory Class: II  
Product Code: KDJ  
Dated: July 30, 2015  
Received: July 31, 2015

Dear Tiffany Lin,

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" (21CFR 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)

K152129

Device Name

FlexiCap Disconnect Cap with Povidone-Iodine Solution (5C4456)

Indications for Use (Describe)

This device is intended for use in the treatment of patients with renal failure to isolate the Luer patient line connector of the Baxter APD (Automated Peritoneal Dialysis) disposable set during temporary disconnections and during the dwell phase of therapy.

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:

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## Indications for Use

510(k) Number (if known)

K152129

Device Name

MiniCap with Povidone-Iodine Solution (5C4466P)

Indications for Use (Describe)

This device is a plastic disconnect cap for peritoneal dialysis and contains povidone-iodine intended to protect the female Luer connector of the Baxter transfer set.

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

July 30, 2015

### **OWNER:**

Baxter Healthcare Corporation  
One Baxter Parkway  
Deerfield, Illinois 60015

### **CONTACT PERSON:**

Tiffany Lin  
Manager, Regulatory Affairs  
32650 N Wilson Road  
Round Lake, IL 60073  
Telephone: (224) 270-4343  
Fax: (224) 270-4119

### **IDENTIFICATION OF THE DEVICE:**

**Common Name:** Disconnect Cap

**Trade Name or Proprietary Name:** FlexiCap Disconnect Cap with  
Povidone-Iodine Solution (5C4456)

**Classification Panel:** 78 Gastroenterology/Urology

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

**Class:** Class II

**Product Code:** KDJ

**Table 1. Baxter Product Code**

Code Number	Name
5C4456	FlexiCap Disconnect Cap with Povidone-Iodine Solution

**PREDICATE DEVICE:**

**Table 2. Predicate Device**

<b>Device</b>	<b>Company</b>	<b>Predicate 510(k)</b>	<b>Clearance Date</b>
High Dose Disconnect Cap and MiniCap with Povidone-Iodine, High Dose Disconnect Cap with Povidone-Iodine	Baxter Healthcare Corporation	K972579	October 1, 1997

**DESCRIPTION OF THE DEVICE:**

The FlexiCap Disconnect Cap with Povidone-Iodine Solution (FlexiCap) is a single use device that connects to the patient line connector of the Baxter Automated Peritoneal Dialysis (APD) set and is designed to isolate the line during temporary disconnections and the dwell phase of peritoneal dialysis therapy sessions. The FlexiCap consists of a molded low density polyethylene cap which contains a polyurethane foam sponge and 10% povidone-iodine (PVP-I) solution.

**INDICATIONS FOR USE:**

**Device Name:**

FlexiCap Disconnect Cap with Povidone-Iodine Solution (5C4456)

**Indications for Use:**

This device is intended for use in the treatment of patients with renal failure to isolate the Luer patient line connector of the Baxter APD (Automated Peritoneal Dialysis) disposable set during temporary disconnections and during the dwell phase of therapy.

**TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:**

The proposed device has equivalent technological characteristics as Baxter's currently legally marketed FlexiCap cleared under 510(k) premarket notification K972579 (cleared October 1, 1997). The intended use, design and function of the proposed device are equivalent to the predicate device.

## **DISCUSSION OF NONCLINICAL TESTS:**

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

### **Performance Data:**

The following bench tests were conducted to evaluate the functional performance of the FlexiCap:

- Torque-On Test
- Leak Test
- Iodine Efficacy Test

All tests met the acceptance criteria.

### **Biocompatibility:**

No new materials of construction are being introduced into the FlexiCap. Materials found in the FlexiCap have been previously cleared under 510(k) premarket notification K972579 (cleared October 1, 1997).

Biocompatibility assessments for the FlexiCap were conducted in accordance with ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” for Surface Device, Skin Contact, Permanent Contact Duration, and FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993.” The battery of testing included the following tests:

- Cytotoxicity
- Irritation/Intracutaneous
- Sensitization

## **CONCLUSION:**

The non-clinical data support the safety of the proposed device and demonstrate that the proposed device performs comparably to the predicate device that is currently marketed for the same intended use.

## Section 5. 510(k) Summary

July 30, 2015

### **OWNER:**

Baxter Healthcare Corporation  
One Baxter Parkway  
Deerfield, Illinois 60015

### **CONTACT PERSON:**

Tiffany Lin  
Manager, Regulatory Affairs  
32650 N Wilson Road  
Round Lake, IL 60073  
Telephone: (224) 270-4343  
Fax: (224) 270-4119

### **IDENTIFICATION OF THE DEVICE:**

**Common Name:** Disconnect Cap

**Trade Name or Proprietary Name:** MiniCap with Povidone-Iodine Solution (5C4466P)

**Classification Panel:** 78 Gastroenterology/Urology

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

**Class:** Class II

**Product Code:** KDJ

**Table 1. Baxter Product Code**

<b>Code Number</b>	<b>Name</b>
5C4466P	MiniCap with Povidone-Iodine Solution

**PREDICATE DEVICE:**

**Table 2. Predicate Device**

<b>Device</b>	<b>Company</b>	<b>Predicate 510(k)</b>	<b>Clearance Date</b>
Disconnect Caps Product Codes 5C4212 and 5C4466	Baxter Healthcare Corporation	K895631	January 29, 1990

**DESCRIPTION OF THE DEVICE:**

The MiniCap with Povidone-Iodine Solution (MiniCap) is a single use device that connects to a Baxter transfer set and is designed to isolate the line between peritoneal dialysis therapy sessions. The MiniCap consists of a molded low density polyethylene cap which contains a polyurethane foam sponge and 10% Povidone-Iodine (PVP-I) solution.

**INDICATIONS FOR USE:**

**Device Name:**

MiniCap with Povidone-Iodine Solution (5C4466P)

**Indications for Use:**

This device is a plastic disconnect cap for peritoneal dialysis and contains povidone-iodine intended to protect the female Luer connector of the Baxter transfer set.

**TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:**

The proposed device has equivalent technological characteristics as Baxter's currently legally marketed MiniCap cleared under 510(k) premarket notification K895631 (cleared January 29, 1990). The intended use, design and function of the proposed device are equivalent to the predicate device.

**DISCUSSION OF NONCLINICAL TESTS:**

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

**Performance Data:**

The following bench tests were conducted to evaluate the functional performance of the MiniCap:

- Torque-On Test
- Leak Test
- Iodine Efficacy Test

All tests met the acceptance criteria.

**Biocompatibility:**

No new materials of construction are being introduced into the MiniCap. Materials found in the MiniCap have been previously cleared under 510(k) premarket notification K895631 (cleared January 29, 1990).

Biocompatibility assessments for the MiniCap were conducted in accordance with ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” for Surface Device, Skin Contact, Permanent Contact Duration, and FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993.” The battery of testing included the following tests:

- Cytotoxicity
- Irritation/Intracutaneous
- Sensitization

**CONCLUSION:**

The non-clinical data support the safety of the proposed device and demonstrate that the proposed device performs comparably to the predicate device that is currently marketed for the same intended use.