October 25, 2019

Baxter Healthcare
Kimberly Garcia
Associate, Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073

Re:  K192705
Trade/Device Name:  MiniCap Extended Life PD Transfer Sets
Regulation Number:  21 CFR 876.5630
Regulation Name:  Peritoneal dialysis system and accessories
Regulatory Class:  II
Product Code:  KDJ
Dated:  September 25, 2019
Received:  September 27, 2019

Dear Kimberly Garcia:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gema Gonzalez -S

for
Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K192705

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.*

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Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
Section 5. 510(k) Summary

September 25, 2019

OWNER:
Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON:
Kimberly Garcia
Associate, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: 224-270-4401
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
Regulation Number: 21 CFR 876.5630
Regulation Name: Set, Administration, For Peritoneal Dialysis
Regulatory Class: Class II
Product Code: KDJ

Table 1. Baxter Product Code(s) for Transfer Sets

<table>
<thead>
<tr>
<th>Baxter Code Number</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>5C4482</td>
<td>MiniCap Extended Life PD Transfer Set with Twist Clamp</td>
</tr>
<tr>
<td>5C4483b</td>
<td>MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short</td>
</tr>
</tbody>
</table>
**PREDICATE DEVICE:**

Table 2. Predicate Device(s)

<table>
<thead>
<tr>
<th>Device</th>
<th>Company</th>
<th>Predicate 510(k)</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extended Life CAPD Transfer Set, Peritoneal Dialysis Titanium Catheter Adapter and Locking Cap for Titanium Catheter Adapter&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Baxter Healthcare Corporation</td>
<td>K152675</td>
<td>10/29/2015</td>
</tr>
</tbody>
</table>

<sup>a</sup> 510(k) K152675 was a bundled submission for both the Extended Life CAPD Transfer Set as well as the Peritoneal Dialysis Titanium Catheter Adapter and Locking Cap for Titanium Catheter Adapter. This 510(k) will only utilize the Extended Life CAPD Transfer Set as a predicate device

<sup>b</sup> Product Code 5C4483 is included within this submission; however, no updates are being made to this device since it was cleared in K152675.

**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 K152675 (cleared on October 29, 2015). The intended use, design and function of the proposed devices are equivalent to the predicate device.

**Table 3. Device Comparison**

<table>
<thead>
<tr>
<th>Features</th>
<th>Current Transfer Sets</th>
<th>Proposed Transfer Sets</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td>This set is used during Peritoneal dialysis therapy to transfer peritoneal dialysis solution to the</td>
<td>Same</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Table 3. Device Comparison

<table>
<thead>
<tr>
<th>Features</th>
<th>Current Transfer Sets</th>
<th>Proposed Transfer Sets</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>patient catheter from the source solution container.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indications for use</td>
<td>This set is used during Peritoneal dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Do not use povidone-iodine to connect the Transfer Set to the Baxter Titanium Adapter if there is a known history of allergic reaction to iodine. Use other disinfectants or antiseptic agents that do not contain iodine, hydrogen peroxide, alcohol or bleach.</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile</td>
<td>Yes (EO)</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-Pyrogenic</td>
<td>Yes</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Fluid Path Materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubing 5C4482</td>
<td>Silicone (Dichlorobenzoyl Peroxide Cured)</td>
<td>Silicone (Platinum Cured)</td>
<td>The proposed tubing material has passed functional testing for its intended use. Design control activities have confirmed that there is no impact to safety or effectiveness.</td>
</tr>
<tr>
<td>Tubing 5C4483</td>
<td>Silicone (Dichlorobenzoyl Peroxide Cured)</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Female Connector 5C4482/5C4483</td>
<td>Polyester</td>
<td>Same</td>
<td>N/A</td>
</tr>
<tr>
<td>Catheter Adapter 5C4482/5C4483</td>
<td>Polyester</td>
<td>Same</td>
<td>N/A</td>
</tr>
</tbody>
</table>

DISCUSSION OF NONCLINICAL TESTS:
Baxter Healthcare Corporation conducts risk analysis to determine the design verification tests that need to be conducted based on the change being proposed. 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 based on the change to the material from Dichlorobenzoyl peroxide cured silicone to platinum cured silicone:

- Visual Inspection
- Initial Pressure Test (clamp in closed position)
- Cycling (Conditioning Step Prior to Pressure Tests)
- 8 psi Pressure Test Post Cycling (clamp in closed position)
- 8 psi Pressure Test Post Cycling (clamp in open position)
- 5 lb Pull of Tubing to Barb Connections

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 long-term contact 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 Guidance Document, Use of International Standard ISO 10993-1: Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (Issued June 16, 2016). The battery of testing included:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute Systemic toxicity
- Material Mediated Pyrogenicity
- Sub-chronic Toxicity
- Genotoxicity
- Hemolysis
- Physical or Chemical Information (Extractables & Leachables)
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.