March 12, 2024

Baxter Healthcare
Brad Roynon
Associate Director, Regulatory Affairs
2512 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K231849
Trade/Device Name: MiniCap Extended Life PD Transfer Set with Twist Clamp - Code 5C4482A; MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Short - Code 5C4483
Regulation Number: 21 CFR 876.5630
Regulation Name: Set, Administration, For Peritoneal Dialysis
Regulatory Class: Class II
Product Code: KDJ
Dated: February 15, 2024
Received: February 15, 2024

Dear Brad Roynon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Maura Rooney -S

Maura Rooney
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231849

Device Name
MiniCap Extended Life PD Transfer Set with Twist Clamp - Code 5C4482A
MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Short - Code 5C4483

Indications for Use *(Describe)*
These sets are 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
PRAStaff@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."

Baxter

Section 5. 510(k) Summary

JUNE 23, 2023

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Brad Roynon
Assoc. Director, Global Regulatory Affairs
Kidney Care PD
25212 W. Illinois Route 120
Round Lake, IL 60073
Telephone: +1.262.581.7157
Fax: +1.224.270.4119

IDENTIFICATION OF THE DEVICE:

Common Name: Transfer Sets
Trade/Device Name:
MiniCap Extended Life PD Transfer Set with Twist Clamp – Code 5C4482A
MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short – Code 5C4483
Classification Panel: 78 Gastroenterology/Urology
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: KDJ

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

Baxter Code Number	Name
5C4482A	MiniCap Extended Life PD Transfer Set with Twist Clamp
5C4483	MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short

Baxter

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
MiniCap Extended Life PD Transfer Sets	Baxter Healthcare Corporation	K152675	10/29/2015

DESCRIPTION OF THE DEVICE:

The MiniCap Extended Life PD Transfer Set with Twist Clamp – Code 5C4482A and MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short – Code 5C4483 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 allow for the exchange of peritoneal dialysis solution into and out of the peritoneal cavity as prescribed.

INDICATIONS FOR USE:

These sets are 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 devices have 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

Features	Predicate Device Cleared under K152675	Proposed Device Transfer Sets	Discussion of Differences
Intended Use	This set is used during Peritoneal dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container.	These sets are used during Peritoneal Dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container.	N/A

Baxter

Table 3. Device Comparison

Features	Predicate Device Cleared under K152675	Proposed Device Transfer Sets	Discussion of Differences
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.	These sets are used during Peritoneal Dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution container.	N/A
Contraindications	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.	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 or chlorhexidine gluconate.	Under a previous change, chlorhexidine gluconate was added to the Contraindications section.
Sterile	Yes (EO)	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	Yes	Same	N/A
Fluid Path Materials			
Tubing 5C4482A/5C4483	Silicone (Dichlorobenzoyl Peroxide Cured)	Silicone (Platinum Cured)	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.
Female Connector 5C4482A/5C4483	Polyester	Same	N/A
Catheter Adapter 5C4482A/5C4483	Polyester	Same	N/A

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 the idea 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 devise 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 both open and closed position)
- 5 lb Pull of Tubing to Barb Connection
- Functionality after Iodine Exposure (over 48 hours continuous and 6 months simulated use)
- Flow Rate (after iodine exposure)
- Shelf Life

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 10993-1, "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
- Implantation
- Hemolysis

In addition, extractables and leachables was performed and a toxicological evaluation completed for the change to platinum cured silicone. The extractables and leachables testing was performed per ISO 9003-18:2020, "Biological evaluation of medical devices – Part 18: Chemical characterization of materials". The toxicological evaluation was performed per ISO 10993-17:2002, "Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances".

- Physical or Chemical Information (extractables & leachables)
- Toxicological Evaluation

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.