November 19, 2020

Baxter Healthcare Corporation
Brad Roynon
Sr. Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073

Re: K201867
Trade/Device Name: Homechoice Claria Automated Peritoneal Dialysis (APD) System, Sharesource Connectivity Platform for Use with the Homechoice Claria APD System
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: FKX
Dated: October 8, 2020
Received: October 19, 2020

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 (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.

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201867

Device Name
Homechoice Claria APD System
&
Sharesource Connectivity Platform for use with the Homechoice Claria APD System

Indications for Use *(Describe)*
Homechoice Claria APD System:
Baxter's Homechoice Claria APD system is intended for automatic control of dialysis solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis in the HOME HEALTHCARE ENVIRONMENT including comparable use in professional healthcare facilities.

Sharesource Connectivity Platform for use with the Homechoice Claria APD System:
The Sharesource portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This system is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

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.

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Section 5. 510(k) Summary

DATE:

October 14, 2020

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

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Round Lake, IL 60073
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Fax: (224) 270-4119

IDENTIFICATION OF THE DEVICE:

Common Name: Automated Peritoneal Dialysis System
Trade/Device Name: Homechoice Claria Automated Peritoneal Dialysis (APD) System**Classification Panel:** 78 Gastroenterology and Urology
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis sytem and accessories
Regulatory Class: Class II
Product Code: FKX

Common Name: Peritoneal Dialysis Software
Trade/Device Name: Sharesource Connectivity Platform for Use with Homechoice Claria APD System**Classification Panel:** 78 Gastroenterology and Urology
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis sytem and accessories
Regulatory Class: Class II
Product Code: FKX

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Table 1. Product Codes in this Submission

Product Code	Name
5C6M40	Homechoice Claria APD System
5CGM01	Sharesource Connectivity Platform for Use with the Homechoice Claria APD System

PREDICATE DEVICE:

The Homechoice Claria APD System is substantially equivalent to the HomeChoice/HomeChoice PRO Automated Peritoneal Dialysis personal cyclers, which were previously cleared under 510(k) premarket notification K102936. The Sharesource Connectivity Platform for Use with the Homechoice Claria APD System is substantially equivalent to the Sharesource Connectivity Platform for Use with the AMIA APD System, which was previously cleared under 510(k) premarket notification K151525.

DESCRIPTION OF THE DEVICE:

The Homechoice Claria APD System (Claria) is intended for automatic control of dialysis solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis. The system automatically cycles peritoneal dialysis solution in the amounts and at the times prescribed by a clinician familiar with and well informed about peritoneal dialysis. The clinician may use the Sharesource Connectivity Platform for Use with the Homechoice Claria APD System (Sharesource) to remotely communicate with the Claria cycler. Sharesource allows the transfer of treatment data originating from the treatment device to the clinician for review of historical treatment results. It also allows the clinician to adjust the device settings of the Claria cycler remotely. Changes to the device program by the clinician require the patient to review and accept the changes prior to the implementation of those changes. If the patient does not accept the changes, the Claria cycler will not accept the modified program. Sharesource does not include any real-time monitoring or real-time programming capabilities. A more detailed device description is included in Section 10 of this submission.

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INDICATIONS FOR USE:

Homechoice Claria APD System

Baxter's Homechoice Claria APD System is intended for automatic control of dialysis solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis in the HOME HEALTHCARE ENVIRONMENT including comparable use in professional healthcare facilities.

Sharesource Connectivity Platform for Use with the Homechoice Claria APD System

The Sharesource portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This system is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

TECHNOLOGICAL CHARACTERISTICS

The Homechoice Claria APD System has similar technological characteristics as compared to its' predicate device. The Sharesource Connectivity Platform for Use with the Homechoice Claria APD System has similar technological characteristics as compared to its' predicate device. Risk analysis has been completed and potential hazards associated with the differences in the proposed devices from their predicates have been identified and mitigated. All potential risks were deemed acceptable after mitigation.

DISCUSSION OF NONCLINICAL TESTS:

Performance testing was conducted on the Homechoice Claria APD System with Sharesource to evaluate the functional performance of the device. The performance testing confirms that Homechoice Claria is as safe and effective as the HomeChoice/HomeChoice PRO cycler, and that the Sharesource Platform for Claria is as safe and effective as the Sharesource Platform for Amia.

In summary, Claria and Sharesource have successfully implemented performance requirements and subsequent outputs verifying and validating:

- The design validation meets the user needs and intended use and is substantially equivalent to the predicate.
- Electrical safety, electromagnetic compatibility, and AIM testing was successfully completed for Claria.
- Risk assessment and risk control measures. Hazard analyses confirm that Claria and Sharesource do not perform in an unexpected or unsafe manner.
- Labeling, software including cybersecurity, and Human Factors have been successfully implemented.

CONCLUSION:

Based on demonstrable evidence, the differences between the proposed devices and their predicates described within this submission do not affect the intended use, the fundamental technology or the operating principles of the device, nor do any changes raise safety or effectiveness issues with regard to the Homechoice Claria APD System and the Sharesource Connectivity Platform for Use with the Homechoice Claria APD System.