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5. 510(K) SUMMARY

DATE PREPARED

September 30, 2010

OWNER

Baxter Healthcare Corporation

CONTACT PERSON

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DEVICE NAME

HomeChoice/HomeChoice PRO Automated Personal Cycler

COMMON NAME

Automated Peritoneal Dialysis (APD) Cycler

CLASSIFICATION NAME

Peritoneal dialysis system and accessories per 21 CFR 876.5630

PREDICATE DEVICE

K053512	HomeChoice/HomeChoice PRO Automated Personal Cycler
K012988	HomeChoice/HomeChoice PRO Automated Personal Cycler
K923065	HomeChoice/HomeChoice PRO Automated Personal Cycler

DEVICE DESCRIPTION

The HomeChoice/HomeChoice PRO Automated Personal Cycler is used for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis therapy. The HomeChoice/HomeChoice PRO cycler automates peritoneal dialysis by heating the dialysis solution, pumping the solution to and from the patient, controlling dwell times, accounting for volumes of the solution according to a physician prescribed therapy and recording the ultrafiltration volume produced by the therapy.

STATEMENT OF INTENDED USE

The HomeChoice Automated Personal Cycler is intended for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis.

TECHNOLOGICAL CHARACTERISTICS

The HomeChoice/HomeChoice PRO Automated Personal Cycler with Version 10.4 software intended use and general technological characteristics remain the same as the HomeChoice Automated Personal Cycler predicate device cleared under K053512, K012988 and K923065. It has the same fluid heating, pumping and measurement controls as the predicate device as well as the same safety and effectiveness features, design and materials of construction.

The HomeChoice/HomeChoice PRO Automated Personal Cycler with Version 10.4 software is substantially equivalent to the predicate device.

ASSESSMENT OF NON-CLINICAL DATA

The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates. Device hardware is certified to applicable safety standards.

Full system validation and software verification testing was performed to ensure that the modifications to the HomeChoice/HomeChoice PRO Automated Personal Cycler function as intended and that the modifications did not negatively impact the overall system. Testing included:

- Software validation and verification testing
- Electromagnetic compatibility (EMC) testing
- Electrical safety testing
- Human Factors Testing

The results from the testing demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria.

Electromagnetic compatibility testing (EMC) was conducted according to the IEC 60601-1-2. The modified HomeChoice/HomeChoice PRO device, outlined in this submission, meets the requirements of IEC 60601-1-2.

Electrical safety testing was conducted according to IEC 60601-1. The modified HomeChoice/HomeChoice PRO device, outlined in this submission, meets the requirements of IEC 60601-1.

ASSESSMENT OF CLINICAL DATA

Not Applicable

CONCLUSION

Based upon the results of non-clinical testing, the modified HomeChoice/HomeChoice PRO device is safe and effective, and performs equivalently to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Baxter Healthcare Corporation
c/o Lisa Skeens, Ph.D
Vice President, Global Regulatory Affairs
1620 Waukegan Road
MCGAW PARK, IL 60085

MAR 30 2011

Re: K102936
Trade/Device Name: HomeChoice / HomeChoice PRO Automated Personal Cycler
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: September 30, 2010
Received: October 4, 2010

Dear Dr. Skeens:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102936

Device Name: HomeChoice/HomeChoice Pro Automated Personal Cycler

Indication(s) for Use:

The HomeChoice/HomeChoice Pro Automated Personal Cycler peritoneal dialysis system is intended for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis.

Prescription Use: ☒	Over-the-Counter Use: ☐
21 CFR 801 Subpart D	21 CFR Subpart C

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102936