DEC 0 5 2001

K012988

Renal Division

Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Il 60085-6730

847-473-6030

BAXTER

510(k) SUMMARY
HomeChoice® Personal Cycler Peritoneal Dialysis System

Submitter's name, addresss, phone, fax, contact person	Baxter Healthcare Corporation Renal Division 1620 Waukegan Road McGaw Park, IL 60085 Phone: (847) 473-6079 Fax: (847) 473-6952 Contact: David Curtin
Date prepared	September 4, 2001
Trade name of device	HomeChoice® Personal Cycler Peritoneal Dialysis System
Common name	Automated Peritoneal Dialysis System
Classification name	Peritoneal dialysis system and Accessories (per 21CFR 876.5630)
Substantially equivalent devices	HomeChoice® Personal Cycler Peritoneal Dialysis System [510(k) number K923065]
Description of the device	The HomeChoice® Personal Cycler Peritoneal Dialysis System provides automatic control of dialysate solution exchanges for low fill volume and standard fill volume therapies with software drain logic designed specific to each fill volume range.
Intended use of the device	The HomeChoice® 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.
Comparison of technological characteristics between new and predicate devices	The HomeChoice® Personal Cycler Peritoneal Dialysis System is exactly the same as the predicate device, with the exception that the modified device provides low fill volume mode drain logic for renal failure patients requiring fill volumes of 60 – 1000 mLs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2001

David E. Curtin, R.A.C.
Associate Director, Regulatory Affairs
Baxter Healthcare Corporation
Renal Division, MPR-A2E
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K012988
Trade/Device Name: HomeChoice® Personal Cycler Peritoneal Dialysis System (Models 5C8310, 5C8302, 5C4471 and 5C4469)
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 FKX
Dated: September 6, 2001
Received: September 6, 2001

Dear Mr. Curtin:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: HomeChoice Personal Cycler Peritoneal Dialysis System

Indications for Use:

HomeChoice® Personal Cycler Peritoneal Dialysis System

The HomeChoice® 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.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office Device Evaluation (ODE)

David A. Krepski

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012988

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109

(Optional Format 1/2/96)