K061515

510(K) SUMMARY

SEP 11 2006

Submitter's Name:	Michael C. Garcia
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Contact:	David E. Curtin - (847) 473-6079
Date Prepared:	05/22/2006
Trade Name:	RenalSoft
Common Name:	RenalSoft
Classification Name:	Hemodialysis system and accessories per 21 CFR 876.5620, and Peritoneal dialysis system and accessories per 21 CFR 876.5630
Equivalent Predicate:	Renal Link (K990953)
Device Description:	RenalSoft is designed specifically for nephrology and offers an electronic alternative to the paper medical chart, in accordance with local regulations. RenalSoft provides the functions of a data repository and data query/ reporting system. RenalSoft is a clinical tool that organizes dialysis therapy data to facilitate clinician decision-making and patient care.

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Intended Use:	Renal Soft is designed specifically for nephrology and offers an electronic alternative to the paper medical chart. RenalSoft provides the functions of a data repository and data query/reporting system. This software is not intended to be a substitute for good clinical management practices nor does its operation create decisions or treatment pathways.
Summary of the Technological Characteristics Compared to The Predicate Device:	The general design of RenalSoft is identical to the Renal Therapy Clinical Data Management Software product cleared under K990953. The proposed product does not raise any new safety and effectiveness issues when compared to the predicate product.
Clinical Data:	NA
Conclusions Drawn:	Validation and verification testing was successful in demonstrating that all design requirements have been met. Bench testing was performed on RenalSoft to support substantial equivalence to the predicate device, as well as demonstrating that the device operates as intended and is safe and efficacious.
Additional Information Requested by FDA:	None to date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 11 2006

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

Re: K061515
Trade/Device Name: **RenalSoft**
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Product Code: KPF
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Product Code: FKP
Regulatory Class: II
Dated: May 31, 2006
Received: June 12, 2006

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 (Premarket Approval), it may be subject to such 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 Section 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061515

Device Name: **RenalSoft**

Indications For Use: **RenalSoft**

Renal Soft is designed specifically for nephrology and offers an electronic alternative to the paper medical chart. RenalSoft provides the functions of a data repository and data query/reporting system. This software is not intended to be a substitute for good clinical management practices nor does its operation create decisions or treatment pathways.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061515