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510(k) Summary

Submitter's name: David E. Curtin

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Contact: Robert L. Wilkinson or David E. Curtin

Date Prepared: March 4, 1999

Trade name: Renal Link

Common name: Baxter's Renal Therapy Clinical Data Management Software

Classification Name: Peritoneal dialysis system and accessories, 21 CFR 876.5630
Hemodialysis system and accessories, 21 CFR 876.5820

Equivalent predicate: cyberREN

Intended Use: Renal Therapy Clinical Data Management Software (Renal Link) is designed specifically for nephrology and offers an alternative to the paper medical chart. Renal Link provides the functions of a data repository and data query/reporting system.

Summary of the Technological Characteristics compared to the predicate device Renal Link Clinical Data Management Software (Renal Link) is a software accessory to a medical device based on relational database technology, the same technology as that used by the predicate device.

Clinical data: N/A

Conclusions drawn From tests: All functions of Renal Link have been tested and validated. Based on the validation results, all functions meet their respective required specifications.

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Additional Information Requested by FDA: None

Official Correspondent:

Robert L. Wilkinson
Director, Regulatory Affairs
Renal Division

Prepared by:

David E. Curtin

3-19-99

David E. Curtin, RAC
Manager, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation

Date



JUN 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David E. Curtin, R.A.C.
Manager, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, IL 60085

Re: K990953
Renal Therapy Clinical Data Management
Software (Renal Link®)
Dated: March 19, 1999
Received: March 22, 1999
Regulatory Class: II
21 CFR §876.5630/78 KPF
21 CFR §876.5820/78 FKP

Dear Mr. Curtin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K990953

Device Name: Renal Therapy Clinical Data Management Software

Indications for Use: Renal Therapy Clinical Data Management Software is designed specifically for nephrology and offers an electronic alternative to the paper medical chart. Renal Link provides the functions of a data repository and data query/reporting system.

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

Concurrence of CDRH, Office Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

David W. Seaman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990953

(Optional Format 1/2/96)