



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 1997

Mr. Ulrich Simonsmeier
Chairman
Cybernius Medical Ltd.
Suite 200, Grandin Park Plaza
22 Sir Winston Churchill Avenue
St. Albert, Alberta, CANADA T8N 1B4

Re: K970989
cyberREN®
Dated: April 15, 1997
Received: April 29, 1997
Regulatory class: II
21 CFR §876.5630/Product code: 78 KPF
21 CFR §876.5820/Product code: 78 FKP

Dear Mr. Simonsmeier:

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 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 requirement, 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/dsmmain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2. Indications for Use (previously sent in a different format)

510(k) Number: K970989
Device Name: cyberREN

Indications for use:

cyberREN is a clinical data management system, designed specifically for nephrology, to replace the paper medical chart. Full chart replacement, i.e. a conversion from a paper medical record to an electronic medical record is at the option of the client. The cyberREN electronic chart essentially provides the functions of a data repository and data query / reporting system.

The cyberREN electronic chart has the following properties:

- The chart is access restricted, and requires the entry of an account name and password, which is unique and private to each user of the system.
- Most entries into the chart are made manually by caregivers, and are automatically stamped with the time and date of entry, as well as with the author's electronic signature.
- Elements of the chart cannot be erased. Additionally, an electronic audit trail registers all changes to the chart in duplicate.
- The cyberREN system is intended for multiuser operations - several users can access the system simultaneously. It is a multidisciplinary system, providing services for physicians, nursing staff and other disciplines supplying services in the treatment of kidney disease.

A cyberREN workplace consists of a standard Windows 95 based computer, which hosts the cyberREN user interface program. The workplaces are positioned in the caregivers offices, and at strategic locations in the ward close to where the medical staff are delivering health care services.

The cyberREN system is used to:

save clinical information - the majority of clinical data maintained by the cyberREN data repository is entered manually by caregivers, while other data is received from

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Dale R. Rathbone
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
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Prescription use ✓
(Per 21 CFR 801.109)

OR

Over The Counter Use _____

networked systems, specifically laboratory results. Data describing the ongoing dialysis process is received directly from the Fresenius 2008H dialysis machine and entered into the cyberREN medical record.

calculate values -

cyberREN calculates a limited number of values, based on laboratory data received and data entered manually. Calculated values are summarized below:

- weight gain between dialysis sessions, calculated with every new dialysis session charted
- protein catabolic rate, percent urea reduction, and the KT/V dialysis efficacy index, typically calculated as a measure of observed treatment efficiency once per month based on patient weights and pre and post dialysis urea laboratory results.
- nutrition parameters, e.g. desired calorific intake being the simple sum of recommendations entered by the caregiver, i.e. to account for normal metabolic consumption, activity, stress and desired weight gain. A calculation for desired protein intake is also carried out, based on the simple product of an **ideal body weight** and upper and lower limits of a **protein intake range**, both parameters entered by the caregiver. These values are displayed on the screen, together with the entered parameters upon which the calculation is based.

display clinical information -

both data entered manually or received from other computer systems or dialysis machines are displayed at the cyberREN workplaces throughout the facility. Approximately 300 computer displays are provided to show various elements of the medical chart. Special displays combine information from several sections of the chart on a single display.

report clinical information -

data entered manually or received from other computer systems may be compiled into a printed report, which contains information from

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various parts of the electronic chart. Approximately 70 predefined reports are available for printout.

General Charting

- patient demographics - cyberREN is used to register patients' personal information, contacts, insurance carriers, social conditions, renal diagnoses, treatment institute, treatment modality, etc.
- patient problems - cyberREN allows the medical staff to maintain a problem list for each patient. Other elements of the chart, e.g. medications, may be linked to one of the problems in the Problem List.
- orders/ order processing - cyberREN registers orders initiated by the physician and presents these on further displays, where they are important for the caregiver. cyberREN also requires the physician to verify verbal or telephone orders, and allows caregivers to document that the orders have been completed.
- medications - cyberREN allows physicians to order medications by selecting the medication by name, and defining its dosage, route to be administered and frequency, among other parameters.
- progress notes / patient encounters - physicians and other caregivers may enter free text notes which describe the results of an encounter with the patient. The user may assign a CPT code to the patient encounter for billing purposes.
- consultations - cyberREN allows the caregiver to keep track of all consultations external to the treating facility. The nature and purpose of the consultation as well as the consulting physician and the consultation's results may be entered into and subsequently reported by the cyberREN system
- laboratory results reporting - cyberREN receives laboratory results for individual patients and displays these on lab result screens or on reports. Results may enter the cyberREN system through manual data entry or through automated electronic data import from a dedicated laboratory computer system or hospital system. Standard communication protocols (HL7), ASCII file import as well as custom communication protocols are employed in the import process

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- billable services - cyberREN registers all billable services in a journal for subsequent reporting and submission to a computer system, whose function is billing claim preparation and reconciliation.
- Nutrition - the nutritionist and dietary staff may use cyberREN to document their goals and objectives for the patient as well as the patients nutritional status i.e. current diet etc. cyberREN may also be used to document nutritionists recommendations for fluid intake and intake of other important elements such as protein, potassium etc..

Hemodialysis

- hemodialysis treatment orders - cyberREN registers orders for the hemodialysis prescription created by the physician. Caregivers may display or print the order for an individual patient when setting up the hemodialysis machine for a treatment on a given day.
- hemodialysis session charting - cyberREN is used by the medical staff administering the hemodialysis treatment to register the patients condition that the start and end of treatment as well as during the treatment. All medical events occurring during treatment, including medications administered, may be entered by medical staff for later query and reporting.
cyberREN may automatically obtain current treatment parameters directly from the dialysis machine for entry into the hemodialysis treatment log. Entries may be checked or made manually by medical staff as well.
A maximum of 30 dialysis machines may be monitored by a Intel Pentium based cyberREN system.
- hemodialysis access charting - cyberREN may be used to document the hemodialysis access i.e. medical procedures creating or correcting the access, as well as to document problems occurring with the access.
- patient/ward hemodialysis schedule - users may enter and view the hemodialysis schedule i.e. the use of hemodialysis machines by the patient population, to assist in scheduling activities.

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Peritoneal Dialysis

peritoneal dialysis orders - cyberREN registers orders for the peritoneal dialysis prescription created by the physician. Caregivers may display or print the order for an individual patient when administering the treatment or when advising the patient of therapy changes.

peritoneal dialysis session charting - cyberREN is used by the medical staff, administering the peritoneal dialysis treatment within the facility, to register the patient's condition that the start and end of treatment as well as during the treatment. All medical events occurring during treatment may be entered by medical staff for later query and reporting.

peritonitis charting - episodes of peritonitis, which the patient has experienced may be entered into the cyberREN system for later query and reporting.

peritoneal access charting - cyberREN may be used to document the peritoneal dialysis access i.e. medical procedures creating or correcting the access, as well as to document problems occurring with the access.

Transplant

transplant status - the caregivers may use cyberREN to document the patient's status on the Transplant List (list of transplant candidates).

transplant workup - caregivers may use cyberREN to register and follow up on the activities required for preparing the patient for a possible kidney transplant.

cyberREN does not:

- logically alter information entered by medical staff, or imported directly from other systems,
- make any recommendations for treatment or treatment parameters,
- influence the operation of the Fresenius 2008H dialysis machine in any way. Communications with the 2008H device is uni-directional, with cyberREN receiving data at a predefined schedule determined by the dialysis machine.
- provide a diagnosis or provide a selection of possible diagnoses.

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