NOV 6 1998

510(k) SUMMARY

SUBMITTER: Bonnie Nakayama, RN, CNN, MBA
KayBath, Inc.
95-1509 Ainamakua Drive, #32
Mililani, HI 96789
Phone: (808) 626-0234

CONTACT PERSON: Bonnie Nakayama

DATE PREPARED: August 1, 1998

DEVICE NAME: Dialysate Concentrate for Hemodialysis (Liquid or Powder)

CLASSIFICATION NAME: Concentrate Solutions for Hemodialysis
Accessories to Hemodialysis

PREDICATE DEVICE: Fresenius USA, Acid Concentrate for Bicarbonate Dialysis

Device Description:

KayBath hemodialysis concentrate solutions contain various salts (sodium, magnesium, calcium and potassium), along with dextrose and glacial acetic acid. Pharmaceutical grade water, produced by a reverse osmosis pump under AAMI Standards, is used to mix the salts, dextrose and acetic acid. The solution is formulated and intended for the express purpose of performing hemodialysis. The acidified dialysate is proportioned inside commercially available hemodialysis machines with water and bicarbonate dialysate. The three streams of liquid unite to become the dialysate that runs countercurrent to the blood through the dialyzer at 500cc/min. See Table 6-1. The hemodialysis device provides the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate. The dialyzer consists of hundreds of hollow strands of a cellulosic or synthetic membrane inside a cylinder. The membrane serves as a selective barrier to the passage of molecules beyond a certain molecular

weight. While the blood travels through the hollow strands, undesirable substances in the blood, such as urea, nitrogen, potassium, etc., pass through the semipermeable membrane into the dialysate and are flushed down the drains.

PROPORTIONING RATIO		
Stream 1	Stream 2	Stream 3
water	bicarbonate dialysate	acid dialysate
42.28	1.72	1

TABLE 6-1

The clinical application of high-efficiency and high-flux treatments in the 1980s carefully defined the dialysate composition used to achieve a stable dialysis treatment. Table 6-2 shows the typical composition of dialysate components used in commonly prescribed high-efficiency and high-flux treatments. A sodium concentration of 140-142 mEq/L provides the best ionic concentration for achieving isotonic ultrafiltration in patients during dialysis, so that excess water loss from the blood is averted. The presence of acetic acid in the acid concentrate provides the appropriate pH controls to prevent calcium carbonate precipitation in the proportioning and valve systems. Precipitation of calcium carbonate in the proportioners can score their internal aspects and freeze up the proportioning systems. The use of 4 mEq/L of acetic acid in the final acid concentrate provides a safety margin to ensure the pH of the dialysate is between 7.1 and 7.4. The small amount of acetic acid is metabolized in the patient to bicarbonate and provides additional buffer capacity.

TYPICAL COMPOSITION of DIALYSATE		
Sodium		100 mEq/L
Potassium		0 to 3 mEq/L
Calcium		2.5 to 3.5 mEq/L
Magnesium		0.75 to 1 mEq/L
Acetic Acid		2.5 to 4.5 mEq/L
Chloride		100 to 107 mEq/L
Dextrose		0 to 200 mg/dl

TABLE 6-2

Since different patients require different removal rates of certain substances, like calcium and potassium, a variety of different acidified dialysate formulas will need to be available:

COMMONLY PRESCRIBED FORMULAS		
Series No.	Potassium	Calcium
4	1 mEq/L	0 mEq/L
5	1 mEq/L	2.5 mEq/L
6	1 mEq/L	3.0 mEq/L
7	2 mEq/L	0 mEq/L
8	2 mEq/L	2.5 mEq/L
9	2 mEq/L	3.0 mEq/L

TABLE 6-3

Predicate Devices:

KayBath acidified concentrate solutions are substantially equivalent to Fresenius USA hemodialysis concentrates in composition, intended use, packaging and labeling, in addition to all the other makers of this solution. The composition is quite precise and uniform. There are no significant differences between those marketed products and this proposed device.

Device Name:	Fresenius USA Naturalyte Acid Concentrate for Bicarbonate Dialysis
Intended Use:	Bicarbonate Dialysis Bath Concentrate Solution
510(k) Number:	K810925
Approval Date:	April 6, 1981
FDA Regulatory Class:	II

Intended Use:
KayBath acid concentrate for bicarbonate dialysis is indicated in the treatment of acute and chronic renal failure during the hemodialysis procedure, with the appropriate hemodialysis machine. This indication statement is essentially the same as the indication statement of the predicate device.

Technological Characteristics:
In comparing the proposed device to the predicate device, both devices utilize the same range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:
No in vitro testing was performed to determine the chemical composition and range of composition at this time. There are no important descriptive differences in comparison to the currenlty marketed product. The descriptive characteristics are precise enough to ensure comparability will be achieved when the proposed device is produced according to this description.

Clinical Test Results:
Clinical testing was not performed.

Conclusions:
KayBath concentrate solutions for bicarbonate dialysis will be safe, effective, and perform as well as the predicate device, when used in accordance with industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Ms. Bonnie Nakayama, R.N., C.N.N., M.B.A.
KayBath, Inc.
95-547 Ukee Street, #110
Waipahu, HI 96797

Re: K982813
Concentrate Solutions for Hemodialysis
Dated: July 15, 1998
Received: August 11, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 KPO

Dear Ms. Nakayama:

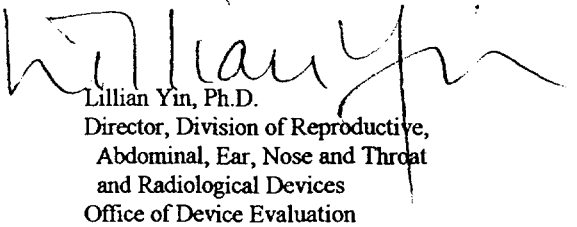
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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

510(k) Number (if known): K982813

Device Name: KayBath Concentrate Solutions for Bicarbonate Hemodialysis

Indications For Use: KayBath acid concentrate dialysate is administered with bicarbonate dialysate and AAMI quality water in a 3 stream proportioning artificial kidney equipment to perform hemodialysis in the ESRD population

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982813

Prescription Use V (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)