Revised

510(K) SUMMARY

510(K) NUMBER:	K973291
SUBMITTER:	Dynamic Technology Corporation 2F. No. 53, Park Ave. II Science-Based Industrial Park Hsinchu Taiwan, R.O.C
DATE PREPARED:	October 6, 1997
DEVICE NAME:	DYNAMIC Hollow Fiber Dialyzer DC-Series
PREDICATE DEVICES:	Cobe CentrySystem 160E, Baxter CF25, Terumo Clirans T175 Dialyzers

Device Description

The membrane used in this device which is substantially equivalent to the membranes utilized in the Cobe CentrySystem 160E and Baxter CF25 Dialyzers, which have been previously approved under a 510(k) Notification (K864831).

Blood enters a blood inlet port where it is distributed to hollow fibers. Each hollow fiber has an inner diameter of 200 microns and a wall thickness of 8 microns. The fibers used in this device are substantially equivalent in design to the previously approved Cobe CentrySystem 160E Dialyzers. The wall thickness of the hollow fibers in Cobe CentrySystem 160E Dialyzers, Baxter CF25 Dialyzers and the proposed device is 8 microns. The inner diameter of hollow fibers in both Baxter CF25 Dialyzers and the proposed device is 200 microns. The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port.

Predicate Devices

The DYNAMIC Hollow Fiber Dialyzer DC-Series Dialyzers are substantially equivalent in construction, design, intended use, and function to other hemodialyzers currently marketed in the United States. The DYNAMIC Hollow Fiber Dialyzer DC-Series Dialyzers are substantially equivalent in function, design, and operation to the Cobe CentrySystem 160E, Baxter CF25, and Terumo Clirans T175 Dialyzers. Which have been previously approved for marketing in the United States.

Intended Use

The DYNAMIC Hollow Fiber Dialyzer DC-Series are indicated for use whenever a patient is in acute or chronic renal failure and hemodialysis is prescribed by a physician. Therefore, use of the device should be only on direction of a physician who has evaluated all of the aspects of the patient's illness. The indication statement is essentially the same as the indication statement of the predicate devices.

Technological Characteristics

Comparing the proposed device to the predicate devices, some similarities are noted in the design and materials employed to accomplish the same intended use. Both the proposed device and Cobe CentrySystem 160E Dialyzers utilize the same hollow fiber membrane. Both the proposed device and Cobe CentrySystem 160E Dialyzers utilize polycarbonate for the header material and polyurethane for the membrane potting material. The proposed devices are sterilized by ethylene oxide gas.

In Vitro Performance

In vitro testing was performed on the proposed device to determine the following: BUN, creatinine, phosphate, and vitamin B12 clearances, and ultrafiltration coefficient. The results are listed on the next page with the data from the predicate devices. The result indicates that the proposed device is substantially equivalent to Terumo Clirans T175 and Baxter CF25 for in vitro performance

Conclusions

Testing performed on the DYNAMIC Hollow Fiber DC-Series indicated that it is safe, effective, and performs as well as the predicate devices, when used in accordance with the instructions for use.

Comparative Data

Model		DYNAMIC DC-160	DYNAMIC DC-190	TERUMO CLIRANS T175	Baxter CF25	COBE CentrySystem 160E
Clearance(ml/min)	BUN	185	190	192	191	--
	Creatinine	167	179	177	170	130
	Phosphate	155	165	151	159	--
	Vitamin B12	67	78	79	62	35
In Vitro Ultrafiltration Coefficient (ml/hr/mmHg)		7.5	9.5	8.8	6.5	4.3
Effective Surface Area (m^2)		1.6	1.9	1.75	1.6	0.9
Number of Fibers		10,300	12,000	11,800	12,000	6,240
Inner Diameter (μm)		200	200	200	200	--
Wall Thickness (μm)		8	8	9	8	8
Sterilization Method		ETO	ETO	ETO	ETO	ETO
Priming Volume (ml)		91	104	120	112	42
Max. TMP (mmHg)		500	500	500	500	--

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Dynamic Technology Corporation
c/o Eric Luo, Ph.D.
6833 Saint Lawrence Street
Plano, Texas 75024

Re: K973291
DYNAMIC DC-160 and DC-190 Hollow Fiber Hemodialyzers
Dated: November 10, 1997
Received: November 18, 1997
Regulatory Class: II
21 CFR §876.5820/Product Code: 78 FJI

Dear Dr. Luo:

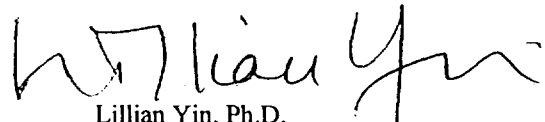
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/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): K973291

Device Name: DYNAMIC Hollow Fiber Dialyzer DC-Series

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973291

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

(Optional Format 1-2-96)