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HAIDYLENA MEDICAL

510(k) SUMMARY

Submitter

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Date summary was prepared

June 15,1998

Name of the device

Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer

Identification of predicate device

The Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer are substantially equivalence in construction, design, intended use, and function to other hemodialyzers currently marketed in the United States. The Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer are substantially equivalence in function, design and operation to the Cobe Centry Syatem 160E, Baxter CF25, and Terumo Clirans T175 Dialyzers, which have been previously approved for marketing in the United States.

Description of the device

The Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer are a family of hemodialyzers developed to provide safe and effective hemodialysis over ranges of dialyzer patient treatment requirements. The membrane used in the device is Cuprophan which is substantially equivalence to the Cuprophan membranes utilized in the cobe centry System 160E and Baxter CF25 Dialyzers, which have been previously approved for marketing in the United States. The Cobe Cnetry System 160E was approved under a 510(k) Notification (K864831). The Cuprpohan membranes utilzed in both Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer and Cobe Centry System 160E Dialyzers are manufactured by Akzo (Enka) of Germany. Cuprophan membrane is also utilized in Baxter CF25 Dialyzers. Hemophan membrane is also manufactured by Akzo (Enka) and is also cellulose membrane but derivative from Cuprophan membrane.

Blood enters a blood inlet port where it is distributed to Cuprophan and Hemophan membrane. 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 equivalence in design to the previously approved Cobe Centry System. The wall thickness of the Cuprophan and Hemophan fibers in Cobe Centry System 160E Dialyzers, Baxter CF25 Dialyzers and the proposed device is 8 microns. The inner diameter o Cuprophan and Hemophan in both Baxter CF25 Dialyzer and the proposed device is 200 microns.

Blood is bumped via a roller pump from the artery of the patient into the arterial end of the dialyzer. The blood travels down through the dialyzer fibers where waste products pass through the membrane of the dialyzer into the dialysate, which is constantly circulating through the dilayzer on the outside of the hollow fibers. Blood then exits the venous end of the dilayzer back to the patient.

Intended use

The Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer are indicated for use whenever a patient is in acute or chronic renal failure and a physician prescribes hemodialysis. Therefore, use of this device should be only on the 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 device, some similarities are noted in the design and materials employed to accomplish the same intended use. Both the proposed device and Cope Centry Sytem 160E Dialyzers utilize the same Cupropohan hollow fiber membrane manufactured by Akzo (Enka) of Germany. Both the proposed device and Cobe Centry Syatem 160E Dialyzers utilize polycarbonate for the header material and polyurethan for membrane potting material. The proposed device and predicate devices are sterilized by ethylene oxide gas.

Design

Hadylena Dialyzer	Cobe Centry system 160E	Baxter CF 25	Terumo Clirance T175
- with assistance of alpha plan company (German company) - according to international standard	The same	The same	The same

Materials

Materials	Haidyelna Dialyzer	Cobe Centry system 160E	Baxter CF 25	Terumo Clirance T175
Housing	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Membrane	AkzoCuprophan & Hemophan	AkzoCuprophan & Hemophan	AkzoCuprophan & Hemophan	AkzoCuprophan & Hemophan
Putting materials	Polyurethane	polyurethane	polyurethane	polyurethane
Blood caps	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Vented caps	Polyethylene	Polyethylene	Polyethylene	Polyethylene

In Vitro Performance

In vitro testing was performed on the proposed device to determine the following: Urea, Creatinine, Phosphate, and Vitamin B12 clearance, and ultrafiltration coefficient. The results are listed on the next page with the data from the predicate device. The result indicates that the proposed device is substantially equivalent to Terumo Clirans T175 and Baxter CF25 for in vitro performance.

Physical	Haidylena Hollow fiber Dialyzer							Terumo Clirans T175	Baxter CF25	Cobe Centry S. 160E
	Cuprophan			Hemophan						
	HL 100	HL 120	HL 130	HL 100 H	HL 120 H	HL 130 H	HL 160 H			
Blood priming volume (ml)	57	68	79	57	68	79	95	120	112	42
Effective surface (S.Q.M.)	1.0	1.2	1.3	1.0	1.2	1.3	1.6	1.75	1.6	0.9
Wall thickness(μm)	8	8	8	8	8	8	8	9	8	8
Clearance (ml/min.)										
Urea	174	179	184	170	175	179	190	192	191	
Cretonne	149	156	162	149	154	160	161	177	170	130
Phosphate	124	138	141	129	140	149	151	151	159	
Vitamin	48	55	58	46	55	60	61	97	62	35
Ultrafiltration rate (ml/hr/mmHg)	4.9	6.0	6.6	4.9	6.0	6.0	8.0	8.8	6.5	4.3
Maximum TMP	500	500	500	500	500	500	500	500	500	

Additional safety Information

Sterilization conditions have been validated according to BS EN 550: Sterilization of medical devices, Validation and remote control of Ethylene oxide sterilization, and AAMI guidelines to provide a Sterility Assurance Level of 10 to the negative sixth.

Ethylene oxide residuals will not exceed the maximum residuals limits proposed for part 821 of Tittle 21 in the Federal register of June 23, 1978 (or as finalized or amended).

Conclusions

Testing performed on the Haidylena Cuprophan and Hemophan Hollow Fiber Dialyzer indicate it is safe, effective, and performs as well as the predicate devices, when used in accordance with instruction for use.

Signature

Sameh Abdel Rahman Tamim
15.06.1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1998

Mr. Sameh Tamim
Laboratories and Sterilization Manager,
Plant Quality Coordinator, and Registration Specialist
Haidylena Medical
26 Makram Ebeid St.
Nasr City, Cairo, Egypt

Re: K982337
Cuprophan and Hemophan Hollow
Fiber Dialyzer
Received: October 23, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 FJI

Dear Mr. Tamim:

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

PREMARKET NOTIFICATION
STATEMENT FOR INDICATIONS FOR USE
[As required by 510(k)]

I certify that, in my capacity as a laboratories and sterilization manager, plant quality coordinator and registration specialist of Haidylena Medical company, that the device submitted in this premarket notification are intended for use whenever a patient is in acute or chronic renal failure and hemodialysis is prepared by a physician. Therefore, use of this device should be only on the direction of a physician who has evaluated all of the aspects of the patient's illness.

Signature

Sameh Tamim

(Typed Name)

Sameh Abdel Rahman Tamim

(Dated)

15/06/1998

(premarket Notification [510 (k)] Numk

✓For Prescription use

See Below

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982337

12/29/98