APR 17 2000



## 510(k) SUMMARY

**SUBMITTED BY:** Lachman Consultant Services, Inc.
U.S. Agent for IDEMSA
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**SUBMITTED FOR:** Investigacion Y Desarrollo de Equipos Medicos, S.A (IDEMSA)
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**DATE PREPARED:** May 28, 1999

**DEVICE NAME:** IDEMSA Hemophan Dialyzer

**COMMON NAME:** Hemodialyzer

**CLASSIFICATION NAME:** Conventional Hemodialyzer, Capillary, Hollow Fiber

**PREDICATE DEVICES:** Haidylena Cuprophan and Hemophan Hollow Fiber, Cobe CentrySystem 160E, Baxter CF25, Terumo Clirans T175 Dialyzers

The proposed family of dialyzers are substantially equivalent in construction, design, intended use, and function to other hemodialyzers currently marketed in the United States. The IDEMSA Hemophan Dialyzers are substantially equivalent in construction, design, intended use, and function to Haidylena Cuprophan and Hemophan Hollow Fiber, Cobe Centry System 160E, Baxter CF25, and Terumo Clirans T175 dialyzers.

### DEVICE DESCRIPTION

The IDEMSA Hemophan Dialyzers are a family of hollow fiber dialyzers that provide safe and effective hemodialysis over ranges of dialyzer patient treatment requirements. The membrane used in the device is Hemophan which is substantially equivalent to the Hemophan membranes utilized in the Haidylena Cuprophan and Hemophan Hollow Fiber dialyzers (cleared for marketing in the United States under 510(k) # K982337). The Hemophan membranes utilized in both IDEMSA Hemophan dialyzers and Haidylena Cuprophan and Hemophan Hollow Fiber dialyzers are manufactured by Membrana GmbH (formerly Akzo (Enka AG)) of Germany. Hemophan® is a modified cellulose membrane that was developed by ENKA to improve the blood compatibility of the regenerated cellulose membrane Cuprophan®. Cuprophan®

membranes utilized in both Cobe CentrySystem 160E dialyzers and Baxter CF25 are also manufactured by the former Akzo (Enka AG). The Terumo Clirans T175 series dialyzers also use a cellulose membrane.

Blood enters a blood inlet port where it is distributed to the Hemophan membrane. The fibers used in the proposed device are substantially equivalent in design to the previously cleared Haidylena and Cobe CentrySystem dialyzers. Each hollow fiber has an inner diameter of 200 microns and a wall thickness of 8 microns. The wall thickness of the Hemophan and Cuprophan fibers in the Haidylena, Cobe CentrySystem 160E, Baxter CF25, and the proposed device is 8 microns. The inner diameter of Hemophan and Cuprophan in the Haidylena, Baxter CF25 dialyzer and the proposed device is 200 microns.

Blood is pumped 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 water waste products pass through the membrane of the dialyzer into the dialysate, which is constantly circulating through the dialyzer on the outside of the hollow fibers. Blood then exits the venous end of the dialyzer back to the patient.

**INTENDED USE**

The IDEMSA Hemophan Hollow Fiber Dialyzers 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 and differences are noted in the design and materials employed to accomplish the same intended use. Both the proposed and predicate device (Haidylena HL 100H dialyzers) utilize the same Hemophan, hollow fiber membrane manufactured by the former Enka AG (currently Membrana GmbH). Both the proposed device and predicate device (Haidylena HL100H dialyzers) utilize polycarbonate for the header material and polyurethane for the potting materials. The proposed and predicate devices are sterilized by ethylene oxide gas. However, the proposed device may also be sterilized by gamma radiation. The proposed device and Terumo Clirans T-175 series dialyzers each contain a silicone rubber "O-ring." The proposed device utilizes polypropylene for the non-blood contact protector cap, a predicate material identified for use in the blood ports for the Terumo Clirans T-175 series dialyzers. A summary comparison is provided on the following page.

## Materials

**Table 1: Predicate Device Comparison / Materials**

| Item | IDEMSA Hemophan Dialyzers | Haidylena HL100H Dialyzers | Cobe Centry System 160E | Baxter CF25 | Terumo Clirans® T-175 |
|---|---|---|---|---|---|
| Potting Materials | Polyurethane | Polyurethane | Polyurethane | Polyurethane | Polyurethane |
| Blood port caps | Polycarbonate | Polycarbonate | Polycarbonate | Polycarbonate | Polypropylene |
| Housing | Polycarbonate | Polycarbonate | Polycarbonate | Polycarbonate | Acrylonitrile-Styrene copolymer |
| "O" rings | Silicone | ---------- | ---------- | ---------- | Silicone |
| Membrane | Hemophan® (modified cellulose) | Hemophan® (modified cellulose) | Cuprophan® (regenerated cellulose) | Cuprophan® (regenerated cellulose) | Cellulose |

## IN VITRO PERFORMANCE

In vitro testing was performed on the proposed device to determine the following: ultrafiltration coefficient; pressure drop across blood and dialysate side; and urea, creatinine, phosphate, and vitamin B12 clearance. Since the proposed dialyzer does not consist of a new or altered design in comparison to the predicate devices, hemocompatibility performance testing was not performed. Bench data developed for the proposed device is provided on the following page. The results of these tests confirmed that the proposed device is substantially equivalent to the predicate devices for these parameters.

## ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the AAMI guidelines to provide a sterility assurance level (SAL) of 10 the negative sixth.

Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the *Federal Register* of June 23, 1978 (or as finalized or amended).

## CONCLUSION

The IDEMSA Hemophan hollow fiber dialyzers submitted in this 510(k) are substantially equivalent in intended use, design, technological characteristics, materials and performance to the predicate device when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2000

IDEMSA
c/o Leon Lachman, Ph.D.
President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: K991908
IDEMSA Hemophan Hollow Fiber Dialyzers
Dated: January 21, 2000
Received: January 24, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJI

Dear Dr. Lachman:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

**IDEMSA**
**510 (k) Notification**
**Hemophan Conventional Dialyzers**

## XIV. INDICATIONS FOR USE

The IDEMSA Hemophan Dialyzer has been designed for use in hemodialysis and associated forms of treatment for chronic or acute kidney failure.

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991908

Prescription Use ✓
(Per 21 CFR 801.109)