AUG 2 5 2000

510(k) SUMMARY
K994198

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Toray Industries (America), Inc.
600 Third Avenue, 5th floor
New York, NY 10016-1921
Telephone: (212) 697-8150
Contact person: Mr. Hidehiko Okubo, Director, Medical and Pharmaceutical

Date of Summary: May 31, 2000

Device Name: Hemofeel™-CH Hemofilter

Device Classification Name: High permeability hemodialysis system (78 KDI); 21 CFR, Part 876.5860

Legally Marketed Devices to which Equivalence is Claimed: The legally marketed predicate devices are the Renal Systems, Inc. Renaflo Hemofilter (K854011), determined to be substantially equivalent to a legally marketed (preAmendment) device on December 5, 1985; and the Toray Industries Filtryzer™ Model BK-U (K935471), determined to be substantially equivalent to a legally marketed (preAmendment) device on May 19, 1995.

Device Description: The Hemofeel-CH Hemofilter consists of highly permeable polymethylmethacrylate (PMMA) hollow fibers housed in a polystyrene casing and secured at each end with polystyrene headers. Blood enters the device through the arterial inlet port, passes through the hollow fibers and exits at the opposite end through the venous outlet port. The Hemofeel-CH hemofilter is provided in a range of sizes based on the surface area of the hollow fiber membrane. Hemofilter size should be selected by the physician according to the patient's body weight and medical condition. The device is gamma-ray sterilized and intended for single use only.

Intended Use: The Hemofeel™-CH hemofilter is indicated for use in the prevention or treatment of fluid overload, electrolyte and acid/base imbalances in cases of acute renal failure or toxemia with oliguria or anuria. It may also be used when removal of excess fluid is indicated, such as patients in pulmonary edema or congestive heart failure refractory to diuretic therapy.

Descriptive Summary of Technological Characteristics and Those of Predicate Devices: The features and capabilities of the Hemofeel are identical to those of the Renaflo Hemofilter. The two devices are similar in dimensions. For example, the two devices have essentially identical inner diameter, casing length, fiber length, membrane surface area, and blood volume. These similarities will logically result in substantially equivalent performance characteristics. Both the Hemofeel and the Filtryzer employ a PMMA membrane to filter the blood and remove toxins.

Performance Data:

In Vitro Testing: Ultrafiltration coefficient testing, water permeability and pressure drop testing were conducted on the Hemofeel-CH hemofilter. All samples met the acceptance criteria. Hemolysis testing was also carried out on the device, with no hemolysis seen. These test results establish that the Hemofeel-CH hemofilter possesses performance characteristics that make it acceptable for its intended use.
Shelf life testing was conducted to establish the validity of the labeled three-year shelf life of the device. The results of the testing establish that biological, sterility, leak and water permeability characteristics are maintained at the end of the labeled shelf life.

Clinical: The Hemofeel-CH hemofilter was evaluated in the clinical setting in eight anuric critically ill patients. Continuous hemofiltration was found to be useful for the management of fluid and electrolyte balance in acute renal failure. There were no complications related to the use of the Hemofeel hemofilter. The data and information from the clinical study indicate that the Hemofeel is safe and effective for use in continuous hemofiltration.

Conclusion: The information and data provided in this 510(k) Notification establish that the Hemofeel-CH hemofilter is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2000

Toray Industries (America), Inc.
c/o Ms. Lisa S. Jones, R.A.C.
Devices for the Future
540 College Street
Bellaire, TX 77401-5010

Re: K994198
Hemofeel™ - CH Hemofilter
Dated: May 31, 2000
Received: June 1, 2000
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Ms. Jones:

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)

May 31, 2000

510(k) Number: K994198

Device Name: Hemofeel™-CH Hemofilter

Indications for Use: The Hemofeel™-CH hemofilter is indicated for use in the prevention or treatment of fluid overload, electrolyte and acid/base imbalances in cases of acute renal failure or toxemia with oliguria or anuria. It may also be used when removal of excess fluid is indicated, such as patients in pulmonary edema or congestive heart failure refractory to diuretic therapy.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994198

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)