SECTION II Summary and Certification

DEC 19 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CLIRANS® T-Series Hollow Fiber Dialyzer

Classification Name: Dialyzer, Capillary, Hollow Fiber

Common Name: Hollow Fiber Dialyzer

INTENDED USE

The CLIRANS® T-Series Hollow Fiber Dialyzers are devices used as part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. This device is indicated for single and multiple use.

DESCRIPTION

The CLIRANS® T-Series Hollow Fiber Dialyzers consists of cellulose hollow fibers with 9μ wall thickness. 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 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.

SUBSTANTIAL EQUIVALENCE

The CLIRANS® T-Series Hollow Fiber Dialyzers submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the largest effective surface area dialyzer (CL*M151L) cleared in the CLIRANS® TAF Hollow Fiber Dialyzer 510(k) K854280.

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PRINCIPLE OF OPERATION/TECHNOLOGY

The CLIRANS® T-Series Hollow Fiber Dialyzers operate in the following manner. Blood is taken from the artery of a patient and pumped via a roller pump into the arterial end of the dialyzer. The blood travels down through the dialyzer fibers, and waste products then 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, and back into the veins of the patient.

DESIGN/MATERIALS

Parts	CLIRANS T-Series Hollow Fiber Dialyzer	Cleared CLIRANS TAF Hollow Fiber Dialyzer K854280
Hollow Fiber	Cellulose	Cellulose
Housing	Acrylonitrile-Styrene copolymer	Acrylonitrile-Styrene copolymer
Blood Port	Polypropylene	Polypropylene
Screw ring	Acrylonitrile-Styrene copolymer	Acrylonitrile-Styrene copolymer
O-ring	Silicone rubber	Silicone rubber
Adhesive	Polyurethane	Polyurethane
Blood/Dialysate Port cap	Polyethylene	Polyethylene

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SPECIFICATIONS

Parts	CLIRANS T-Series Hollow Fiber Dialyzer			Cleared CLIRANS TAF Hollow Fiber Dialyzer K854280 - *Largest Effective Surface Area (CL*M151L)*
Hollow Fiber	*CL*T150L*	*CL*T175L*	*CL*T220L*	*CL*M151L*
Inside Diameter	200μ	200μ	200μ	220μ
Wall Thickness	9μ	9μ	9μ	12μ
Effective Length	235mm	235mm	235mm	235mm
Quantity of Fiber	10,000pcs	11,800pcs	15,000pcs	9300pcs
Priming Blood Vol	101ml	120ml	148ml	115ml
Eff. Surface Area	$1.5m^2$	$1.75m^2$	$2.2m^2$	$1.5m^2$

PERFORMANCE

The performance of the CLIRANS® T-Series Hollow Fiber Dialyzers (T-Series) are substantially equivalent to the performance of the currently marketed largest effective surface area CLIRANS® TAF Hollow Fiber Dialyzer (CL*M151L). The T-Series dialyzers exhibit a somewhat higher clearance and UFR than the M151L which is to be expected with the thinner fiber walls in the T-Series dialyzer. However, none of the data raises any issues of safety or effectiveness. Therefore, the CLIRANS® T-Series Hollow Fiber Dialyzers performance are substantially equivalent to the predicate devices.

The following clearance tests were performed demonstrating the substantial equivalence of the CLIRANS® T-Series Hollow Fiber Dialyzers submitted in this 510(k) to the largest effective surface area dialyzer (CL*M151L) cleared in the CLIRANS® TAF Hollow Fiber Dialyzer 510(k) K854280.

- Urea
- Creatinine
- Phosphates
- Vitamin B12
- UFR (In Vitro & In Vivo)
- Priming Volume

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ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10 to 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).

Manufacturing control test methods include: functional, extraction and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Prolonged (24 hours-30 days) contact duration]. The blood contacting materials were found to be biocompatible.

The expiration dating for the CLIRANS® T-Series Hollow Fiber Dialyzers will be 36 months. This dating period is adopted from legally marketed CLIRANS® TAF Hollow Fiber Dialyzer 510(k) K854280. The sterilization process and packaging materials are the same for these products. Verification testing of aged product consists of package permeability, sterility and shelf life functional testing.

CONCLUSION

The CLIRANS® T-Series Hollow Fiber Dialyzers submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the largest effective surface area dialyzer (CL*M151L) cleared in the CLIRANS® TAF Hollow Fiber Dialyzer 510(k) K854280. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Date Prepared	February 23, 1997
Prepared by	Keith M. Smith Senior Regulatory Affairs Specialist Regulatory Affairs
Prepared for	Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Phone (410) 392-7375 or (410) 392-7231 Fax (410) 398-6079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Mr. Keith M. Smith
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, Maryland 21921

Re: K970708
CLIRANS® T-Series Hollow Fiber Coventional
Dialyzers for Single and Multiple Use
Dated: November 26, 1997
Received: November 28, 1997
Regulatory Class: II
21 CFR §876.5820/Product Code: 78 FJI and MSE

Dear Mr. Smith:

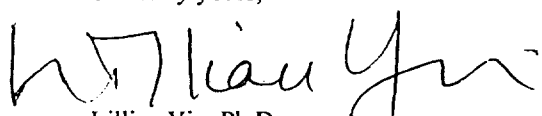
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Device Name: CLIRANS® T-Series Hollow Fiber Dialyzers

Indications For Use:

The CLIRANS® T-Series Hollow Fiber Dialyzers are devices used as part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. This device is indicated for single and multiple use.

(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 K970705

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

(Optional Format 1-2-96)