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SECTION II. SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. ***Device Name***

Proprietary Name	CLIRANS® E-Series Dialyzers
Classification Name	High Permeability Dialyzer
Common Name	Hollow Fiber Dialyzer

B. ***Intended Use***

The CLIRANS® E-series Hollow Fiber Dialyzers are indicated for use whenever a patient is found to be in acute or chronic renal failure and hemodialysis is prescribed by a physician. The device should be used only at the direction of a physician who has evaluated all of the pertinent features of the patient's illness. This device is indicated for single use only.

Note: This is the same intended use as the predicate device – CLIRANS® E-Series Hollow Fiber Dialyzer cleared under K003425.

C. ***Device Description***

The 2.0 m^2 CLIRANS® E and EE Series dialyzers that are the subject of this 510(k) are a larger size (larger fiber surface area) of the currently cleared dialyzers (K003425).

D. ***Principle Of Operation / Technology***

The 2.0 m^2 CLIRANS® E and EE Series dialyzers have the same technological characteristics as the predicate devices.

E. ***Design / Materials***

The 2.0 m^2 CLIRANS® E and EE Series dialyzers have the same design and materials as the predicate devices.

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F. *Specifications*

The 2.0 m^2 CLIRANS® E and EE Series dialyzers have the same specifications as the predicate devices with the exception that they have a larger number of fibers resulting in an increased surface area.

G. *Performance*

The following verification tests were performed to demonstrate the substantial equivalence of the larger surface area device to the devices cleared under K003425 and to the Althin AF-220 dialyzers:

- In Vitro Clearance
- Coefficient of Ultrafiltration, Kuf
- In Vitro kuf
- Pressure Drop in Blood and Dialysate Compartments
- Priming Volume
- Structural Intregrity (Fiber Leak Test)

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

H. *Additional Safety Information*

The CLIRANS® E-Series Dialyzers are classified as Externally Communicating Device, Circulating Blood, Prolonged Contact (24 hrs to 30 days). The device's 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". Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11134 Sterilization of Health Care Products – Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization and EN 554 Medical Devices – Method for Routine Validation and Control of Sterilization. The device is sterilized to a SAL of 10^{-6}.

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I. Substantial Equivalence

The CLIRANS® E-Series dialyzers are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the CLIRANS® E-Series dialyzers cleared under K003425 and to the Althin AF-220 dialyzers cleared under K992573. Differences between the devices do not raise any significant or new issues of safety or effectiveness.

J. Submitter Information

Prepared By: Sandi Hartka
Manager Regulatory Affairs

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Date Prepared: October 22, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Ms. Sandi Hartka
Manager, Regulatory Affairs
Terumo Medical Corporation
125 Blue Ball Road
ELKTON MD 21921

Re: K013550
Trade/Device Name: CLIRANS® E Series Hollow Fiber Dialyzers
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: October 23, 2001
Received: October 24, 2001

Dear Ms. Hartka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 2 0 2001

510(k) Number (if known): K013550

Device Name: CLIRANS® E-Series Hollow Fiber Dialyzers

Indications For Use:

The CLIRANS® E-series Hollow Fiber Dialyzers are indicated for use whenever a patient is found to be in acute or chronic renal failure and hemodialysis is prescribed by a physician. The device should be used only at the direction of a physician who has evaluated all of the pertinent features of the patient's illness. This device is indicated for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013550