

MAR 20 2000

Section I

**510(k) Summary
Required by 21 CFR §807.92**

I. Submitter:

A. Name: Medisystems Corporation

B. Address: 1201 Third Avenue
Seattle, WA 98101-3016

C. Phone and Fax Numbers: Phone: 206-621-6500
Fax 206-621-6501

D. Contact Person: Mr. Fredric Swindler

II. Date of preparation of this Summary: December 17, 1999.

III. Trade name: The access flow reversing valve will have the trade name, Reverso™

IV. Common name: Blood Tubing Set Accessories

V. Classification name: Set, Tubing, Blood, with and without Antiregurgitation Valve

VI. The marketed device(s) to which equivalence is claimed The Medisystems Blood Tubing Set Accessories that are the subject of this submission are substantially equivalent to Blood Tubing Sets marketed by Medisystems and described in Medisystems' Premarket Clearance number K953823.

VII. Product description: A series of blood tubing set accessories to be used as part of the extracorporeal circuit.

VIII. Statement of intended use compared to currently marketed predicate device: Medisystems Blood Tubing Set Accessories are intended for use as part of an extracorporeal blood circuit for hemodialysis. This is identical to the intended use of the legally marketed predicate device, Medisystems Blood Tubing Sets.

IX. Discussion of technological characteristics:

A. Medisystems Blood Tubing Set Accessory, Access Flow Reversing Valve, (Reverso): The technical characteristics of the device consist of a manually operated valve with a gasket to prevent leakage. The device is also equipped with tubing and Luer connectors to allow it to interconnect between the blood tubing set and the blood access devices

The device allows reversal to the arterial and venous blood access without the need to disconnect the blood tubing set from the access devices. The reversal of the arterial and venous accesses is necessary to facilitate certain common diagnostic procedures and can be used to reverse flow in central venous or femoral catheters that have patency problems.

B. Medisystems Blood Tubing Set Accessory, Recirculation Connector: The device is a singly packed recirculation connector (male-to male Luer adaptor) used to interconnect the arterial and venous bloodlines.

C. Medisystems Blood Tubing Set Accessory, Parallel Dialyzer Interconnector: The device is used with a standard blood tubing set to provide a means to connect two dialyzers in parallel into the extracorporeal circuit.

D. Medisystems Blood Tubing Set Accessory, Series Dialyzer Interconnector: The device is used with a standard blood tubing set to provide a means to connect two dialyzers in series into the extracorporeal circuit.

X. Safety and effectiveness: To assure that the devices are safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to; sterility, pyrogenicity, physical testing, and visual examination of both in-process and finished product.

The required testing is defined by written and approved procedures that conform to the product design specifications. This testing for the Medisystems Blood Tubing Set Accessories is defined in detail in the "Device Master Records."



MAR 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fredric G. Swindler
Vice President
Quality Assurance and Regulatory Affairs
Medisystems Corporation
1201 Third Avenue, 39th Floor
Seattle, Washington 98101

Re: K994306
Blood Tubing Set Accessories (Reverso™,
Recirculation Connector, Parallel Dialyzer
Interconnector, and Series Dialyzer
Interconnector)
Dated: December 17, 1999
Received: December 21, 1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 KOC

Dear Mr. Swindler:

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)

Section A

510(k) Number (if known): K994306

Device Name: Blood Tubing Set Accessories

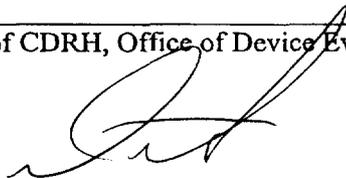
Indications For Use:

Medisystems Blood Tubing Set Accessories are indicated for use as a part of an extracorporeal blood circuit for hemodialysis. The specific indications for use each accessory are as follows:

- a. The Reverso™ is indicated for use as an access flow reversing valve to reverse the blood flow to and from the arterial and venous access devices during hemodialysis procedures without the need to clamp and disconnect bloodlines.
- b. The Recirculation Connector is indicated for use as a male to male Luer adaptor.
- c. The Parallel Dialyzer Connector is indicated for use to interconnect two hemodialyzers in parallel as prescribed by the physician as part of the extracorporeal blood system.
- d. The Series Dialyzer Connector is indicated for use to interconnect two hemodialyzers in series as prescribed by the physician as part of the extracorporeal blood system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use

(Division Sign-Off) Over-The-Counter Use _____
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994306 (Optional Format 1-2-96)