

JAN 30 1998

p. 1/4

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

K973516

Proprietary Device Name: CAPIOX® Hemoconcentrator

Classification Name: High permeability dialyzer

Reason for Submission:

New device.

Intended Use:

The CAPIOX Hemoconcentrator is designed to remove excess fluid from the blood in order to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass.

It is intended to be used during and after surgical procedures requiring cardiopulmonary bypass (up to 6 hours) when the removal of excess fluid from blood is required. It should not be used as a dialyzer, hemofilter or other device.

Description

CAPIOX® Hemoconcentrator consists of Glycerin-free polysulfone fibers, casing, blood port, O-ring and adhesives.

The hemoconcentrator is available in two models. One model has a total membrane surface area of 0.5 m² and the other model has 1.08 m² surface area.

Three types of blood ports are available in each model: ¼" slip, 3/16" slip, and 3/16" lock. The ports are transparent allowing easy observation of air bubbles passing through the ports when priming.

Dimensions of filtrate ports meet the requirements specified in ISO 8637 which permits connection of fast couplings.

The CAPIOX Hemoconcentrator provides high ultra filtration rates which permits the sufficient removal of excess fluid by a slight hydrostatic pressure differential across the membrane without loss of essential plasma proteins.

The CAPIOX Hemoconcentrator provides high ultra filtration rates which permits the sufficient removal of excess fluid by a slight hydrostatic pressure differential across the membrane without loss of essential plasma proteins.

Pre-rinse is not needed. Priming with blood is acceptable.

Substantial Equivalence

The CAPIOX® Hemoconcentrator is substantially equivalent to the Minntech Hemocor HPH Hemoconcentrator (510(k) K923139).as follows:

Intended use: same

Design and Materials

Both devices consist of a tubular casing which contains glycerine-free polysulfone hollow fibers. Blood flows inside the fibers while excess fluid passes through the membrane walls (hollow fibers) to the outside of the fibers and exits through a port in the casing.

Technology and Principles of Operation

Both devices use hollow fiber membrane technology. Some form of pumping mechanism is utilized to maintain blood flow through the extracorporeal circuit and thus through the hemoconcentrator.

Specifications

The specifications for both devices are substantially equivalent. The table below summarizes the major comparisons of the CAPIOX® Hemoconcentrator with the Minntech Hemocor Hemoconcentrator.

Table 1

	CAPIOX Hemoconcentrator	Minntech Hemocor
Intended Use	Used during and after surgical procedures requiring cardiopulmonary bypass when the removal of excess fluid is required. (Should not be used as a dialyzer, hemofilter or for any other function.	Used during and after surgical procedures requiring cardiopulmonary bypass when the removal of excess fluid is required.
Membrane technology	Hollow Fiber	Hollow Fiber
Membrane material	Glycerin-free polysulfone	Glycerin-free polysulfone
Blood flow relative to fiber	Inside	Inside
Effective surface area	HC11: 1.08m ² HC05: 0.5 m ²	HPH1000: 1.1m ² HPH400 : 0.3m ²
Blood Ports	1/4" slip 3/16" slip 3/16" luer lock	1/4" slip
Filtrate ports (*see note)	1/2" Hansen quick connect	1/4" slip
Maximum Blood Flow	500 mL/min	500 mL/min
Maximum transmembrane pressure	500 mmHg	500 mmHg
Priming volume	HC11: 70 mL HC05: 35 mL	HPH1000: 88 mL HPH400 : 34 mL
Priming	No rinse required	No rinse required
Sterilization method	Ethylene oxide	Ethylene oxide

*1/2" Hansen quick connect is the most commonly used filtrate port which is also used in the Baxter HQ-7000, Cobe Hemofilter, and Bard H-4207.

In summary, the CAPIOX® and the Minntech Hemocor HPH Hemoconcentrator are substantially equivalent in intended use, design and materials, technology/principles of operation, specifications and performance. Differences as described above do not raise new issues of safety or effectiveness.

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Additional Safety Information

- Pyrogen Testing
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10⁻⁶.
- 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 testing
- Blood contacting materials were tested in accordance with 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/Limited contact duration).

Date Prepared September 3, 1997

Prepared by: Sandi Hartka,
Manager Regulatory Affairs

for: Terumo Medical Corporation
2100 Cottontail Lane
Somerset, NJ 08873



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandi Hartka
Manager Regulatory Affairs
TERUMO-Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K973516
CAPIOX® Hemoconcentrator
Models CX*HC05, CX*HC11
Dated: December 17, 1997
Received: December 19, 1997
Regulatory Class: III
21 CFR 876.5860/Procode: 78 KDI

JAN 30 1998

Dear Ms. Hartka:

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): K973516

Device Name: CAPIOX® Hemoconcentrator

Indications For Use:

The CAPIOX Hemoconcentrator is designed to remove excess fluid from the blood in order to maintain proper hematocrit and protein concentration during cardiopulmonary bypass and to enable reinfusion of blood remaining in the circuit after bypass.

It is intended to be used during and after surgical procedures requiring cardiopulmonary bypass (up to 6 hours) when the removal of excess fluid from blood is required. It should not be used as a dialyzer, hemofilter or other device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Roderic P. Rathjens
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973516

(Optional Format 1-2-96)