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NOV 13 1998

510(k) SUMMARY

1. Submitter Information:

Name:	Minntech Corporation
Address:	14605 28th Avenue North, Minneapolis, Minnesota 55447
Contact Person:	Mark Murphy
Date Prepared:	September 1, 1998

2. Device Name:

Proprietary name:	Minntech Hemocor HPH® 700 Hemoconcentrator and Tubing Set
Common name:	Hemoconcentrator
Classification name:	Dialyzer, High Permeability per 21 CFR 876.5860

3. Predicate Device:

Hemocor HPH® 1000 Hemoconcentrator

4. Device Description:

The Minntech Hemocor HPH® 700 Hemoconcentrator is made of glycerin-free, microporous, hollow fiber, polysulfone membrane encased in a polycarbonate chamber having molded ultrafiltration ports and polycarbonate blood port header caps. The HPH® 700 TS device has attached PVC 1/4" tubing and accessory polycarbonate adapters for blood path connection. The no-rinse device feature provides versatility for insertion of the hemococentrator into the extracorporeal circuit.

5. Indications for Use:

Device	Indications
Minntech HPH® 700 Hemoconcentrator	The Hemocor HPH® Hemoconcentrator is intended for use as an ultrafiltration system to remove excess fluid during and/or following cardiopulmonary bypass procedures where acute hemodilution has been employed.

6. Technological Characteristics:

A comparative summary of the Hemocor HPH® 700 and predicate device is as follows:

Characteristic	Hemocor HPH® 700 Hemoconcentrator	Hemocor HPH® 1000 Hemoconcentrator
Housing	Polycarbonate	Polycarbonate
Potting Material	Polyurethane	Polyurethane
Membrane	Polysulfone	Polysulfone
Membrane Surface Area	0.7 m^2	1.06 m^2
Maximum Transmembrane Pressure (mmHg)	500	500
Max. Blood Flow rate (ml/min)	500	500
Min. Blood Flow rate (ml/min)	50	100
Priming volume (ml)	58	70
Molecular weight cut-off (daltons)	65000	65000

7. Performance Testing:

The following performance testing was conducted to determine device effectiveness as a hemoconcentrator: Ultrafiltration Rate vs. Transmembrane Pressure, Pressure Drop vs. Blood Flow Rate, Protein Rejection, Minimum Blood Flow Rate & Blood Path Integrity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

Mr. Mark Murphy
Regulatory Affairs Associate
MINNTECH®Corporation
14605 28th Avenue North
Minneapolis, MN 55447

Re: K983085
Hemocor HPH® 700 Hemoconcentrator
and Tubing Set
Dated: September 1, 1998
Received: September 3, 1998
Regulatory Class: III
21 CFR 876.5860/Procode: 78 KDI

Dear Mr. Murphy:

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 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) 594-4613. 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/dsma/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

Indications for Use

510(k) Number (if known): K983085

Device Name: Hemocor HPH 700 Hemoconcentrator

Indications for Use:

The Hemocor HPH 700 Hemoconcentrator is intended for use as an ultrafiltration system to remove excess fluid during and/or following cardiopulmonary bypass procedures where acute hemodilution is employed.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983085