510(k) Summary for the Fresenius Modified F400 and F400TS (Low Volume) Hemoconcentrators

Submitter's Name and Address:	Fresenius Hemotechnology Inc. 110 Mason Circle Suite A Concord, CA 94520
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Contact Person:	Virginia Singer, Manager Regulatory Affairs and Quality Assurance
Date Summary Prepared:	June 21, 1999
Device Trade Name:	Fresenius F Series Low Volume Hemoconcentrator
Common name:	Hemoconcentrator
Classification Name:	High Permeability Hemodialysis System (21 CFR 876.5860)
Substantial Equivalence:	The proposed device is substantially equivalent to the Fresenius F Series F400 Hemoconcentrator
Device Description:	The Low Volume Hemoconcentrator is similar to the F Series F400 Hemoconcentrator. Both hemoconcentrators are hollow fiber-type filters and will be provided with and without a tubing set. The Low Volume Hemoconcentrator has an active membrane surface area of $0.35M^2$ and a priming volume of 27 ml.
Intended Use:	Intended to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate device (See table on next page).

Substantial Equivalence Comparison Chart
Low Volume Hemoconcentrator vs. Predicate F400 Hemoconcentrator

Product Specifications	Low Volume Hemoconcentrator (This submission)	F400 Hemoconcentrator (K974584)
Indication for Use	Intended to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.	Intended to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.
Active Membrane Surface (M^2)	0.35	0.7
Priming Volume (ml)	27	42
Unit Length (with endcaps) (cm)	33	33
Unit Inner Diameter (cm)	2.8	2.8
Number of Fibers	2530	4,600
Fiber Lumen Diameter (μm)	200	200
Fiber Wall Diameter (μm)	40	40
Fiber Length (cm)	22.5	22.5
Fiber Membrane Material	Fresenius Polysulfone	Fresenius Polysulfone
Housing Material	Polycarbonate	Polycarbonate
Potting (resin) Material	Polyurethane	Polyurethane
End Cap	Screw-type, silicone O-ring	Screw-type, silicone O-ring
Blood Connector	Luer connector	Luer connector
Ultrafiltrate Connector (cm, inch)	6.35, ¼	6.35, ¼
Sterilization	EtO	EtO
Pyrogenicity	Non-pyrogenic (LAL assay)	Non-pyrogenic (LAL assay)
Glycerol rinse required	No	No
Molecular Weight Cutoff (daltons)	Approx. 65,000	Approx. 65,000
Max. Transmembrane Pressure (mmHg)	600	600
Max. Blood Flow (ml/min)	300	500
Pressure Drop (mmHg)*		
Nominal, Q_B = 100 ml/min	80.00	32.50
Nominal, Q_B = 200 ml/min	172.50	85.00
Nominal, Q_B = 300 ml/min	270.00	116.25
Ultrafiltration Rate (ml/min)		
Nominal, TMP=525, Q_B = 100 ml/min	46.0	54.0
Nominal, TMP=525, Q_B = 200 ml/min	68.0	84.0
Nominal, TMP=525, Q_B = 300 ml/min	84.7	106.5**

*Pressure Drop and Ultrafiltration Rate will vary according to blood flow rate, transmembrane pressure, temperature, hematocrit and protein concentration.

** Data not previously reported in K974584

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 1999

Ms. Virginia Singer
Manager, Regulatory Affairs and
Quality Assurance
Fresenius Hemotechnology Inc.
110 Mason Circle, Suite A
Concord, CA 94520-1238

Re: K992275
Fresenius F Series Low Volume
Hemoconcentrator
Dated: June 30, 1999
Received: July 7, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Ms. Singer:

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) 594-4613. 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,

CAPT Daniel G. Schultz, M.D.
Acting 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 Statement

510(k) Number (if known):

Device Name: Fresenius F Series Modified F400 and F400TS (Low Volume) Hemoconcentrators

Indications for Use: The Fresenius F Series Hemoconcentrators are indicated to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992275