

MAY 14 1998

K974584
p.1/3

510(k) Summary for the Fresenius F Series Hemoconcentrators

Submitter's Name and Address: Fresenius USA, Critical Care Division
2637 Shadelands Drive
Walnut Creek, CA 94598

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Telefax Number: (510) 988-1932
Contact Person: Virginia Singer

Date Summary Prepared: December 5, 1997

Device Trade Name: Fresenius F Series Hemoconcentrators

Common name: High Flux Hemoconcentrator

Classification Name: High Permeability Hemodialysis System

Legally Marketed Device to which substantial equivalence is claimed: Bard HC40 Hemoconcentrator (K971180)
Amicon Diafilter 30 (K902837)
Minnotech Hemocor HPH 1000 (K923139)
Baxter Bentley Quick Prime HQ 7000 (K903641)
Research Medical Biofilter 140 (K951344 and K970739)

Intended 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.

Device Features:

A complete description of the Fresenius Hemoflow Series Dialyzer, the same product as the F Series Hemoconcentrators, has been submitted in previous premarket notifications. There have been no modifications to this device to adapt it for hemoconcentration. The Fresenius Hemoflow Series Dialyzer is a hollow fiber-type filter. Fresenius-produced polysulfone capillary fibers are bundled and potted with polyurethane into an artificial kidney jacket manufactured from polyurethane. Screw-type end caps, manufactured from polyurethane, have twist lock connectors for the connection of venous and arterial blood lines. Two filtrate ports are located on the side of the filter adjacent to the filtrate chambers. The ports have Hansen-type fittings for connection of filtrate tubing. For hemoconcentration, only the filtrate port on the venous end of the filter is used; the other port on the arterial end is capped.

There are four (4) models within the F Series Hemoconcentrators family. The difference between the four models in the F Series Hemoconcentrators is the number of fibers contained within the artificial kidney jacket. As the number of fibers contained in the filter increases, the diameter of the filter and the filtration capacity increases proportionally. Each model will be manufactured with a tubing set (F400TS, F500TS, F700TS, F800TS); other models will be manufactured with tubing adapter, only (F400, F500, F700, F800).

Technological Characteristics of the Subject Device Compared with Predicate Devices

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree (ODE Guidance Memo #K86-3) was used to make a determination of substantial equivalence (reference Exhibit IV-1 included in this section). The answers to questions identified on this decision tree lead to a determination of substantial equivalence.

1.0 Does the New Device Have the Same Indication Statements?

Yes. The F Series Hemoconcentrators (F400, F500, F700, and F800), Bard HC40 Hemoconcentrator, Amicon Diafilter 30, Minntech Hemocor HPH 1000, Baxter Bentley Quick Prime HQ 7000, and Research Medical Biofilter 140 are all indicated for the removal of excess fluid from blood in cardiopulmonary procedures.

2.0 Does New Device Have Same Technological Characteristics (e.g., design, materials etc.)?

Yes. There are virtually no differences in technology and operation between the F Series Hemoconcentrator devices and the predicate devices. The core of the technology is the filter material within the hemoconcentrators housing. With the exception of the filter manufactured for Research Medical, Inc. (Biofilter 140), the filter material is polysulfone. The diameter of the polysulfone fibers is 200 micrometers, with the exception of the Amicon Diafilter that is 250 micrometers. The filtration capacity of the hemoconcentrator is dependent upon the number of fibers contained in the filter; the more fibers contained, the faster plasma water can be removed. In all marketed filters, plasma water is filtered from the diluted blood and exits the filter from a filtration port located on the side of the filter. Diluted blood enters the filter via the arterial blood port and concentrated blood exits the filter at the venous blood port.

The tubing sets that accompany hemoconcentration filters are virtually identical. They consist of 1/4" ID 3/8" OD PVC tubing with suitable proximal end connectors and line clamps. The tubing set may or may not include a filtrate line, clamps, and filtrate collection bag. These filtrate line items (tubing, adapters, clamps, collections containers) are typically available in an operating room and, therefore, are optional with respect to a tubing kit.

3.0 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although, the structure of the F Series Hemoconcentrator and tubing sets are very similar to the predicate devices manufactured by Fresenius (F40 and F60) and their respective tubing sets, there may be subtle differences in the materials used to manufacture assemblies of other predicate devices (Amicon Diafilter 30, Minntech Hemocor HPH 1000, and Research Medical Biofilter 140) and in the manufacturing methods employed to build these devices. These differences could impact the filtration characteristics and biocompatibility of the product.

Are Performance Data Available to Assess Equivalence?

Yes. All blood/fluid contacting materials of the Fresenius F Series Hemoconcentrators and tubing sets have been subjected to biocompatibility testing consistent with FDA's modified ISO standards for biological evaluation of medical devices.

Comparative in vitro testing of the Fresenius F40, F50, F60, F70, and F80 has been performed to assess end-to-end pressure drop, ultrafiltration rates, concentration rates of cellular blood components, sieving coefficients of a large and a small molecular weight plasma protein, and hemolysis. This testing served to characterize and contrast the performance of the predicate products (F40 and F60) relative to those products for which clearance is being requested (F400, F500, F700 and F800). The testing also served to demonstrate that, at maximum recommended transmembrane pressure and flow rate, the production of plasma hemoglobin was statistically the same for all devices evaluated.

Performance specifications of other hemoconcentrators not manufactured by Fresenius (eg. Amicon Diafilter 30, Minntech Hemocor HP 1000, and Research Medical Biofilter 140) were also compared to Fresenius in vitro data to demonstrate that under similar operating conditions (TMP, blood flow rate, hematocrit, protein content, temperature) filtration performance was relatively the same.

5.0 Does Performance Data Demonstrate Equivalence?

Yes. Based on the results of the testing cited above, Fresenius has demonstrated that:

- The performance of the F Series Hemoconcentrators is consistent with the draft specifications for these products. Performance has been characterized according to a recognized international standard, EN 1283, Haemodialyzers, Haemodiafilters, Haemoconcentrators and Their Extracorporeal Circuits.
- The ultrafiltration and concentration rates of the F Series Hemoconcentrators (F400, F500, F700, and F800) are relative consistent with the rates of predicate devices (F40 and F60) as demonstrated in in vitro studies. Differences in rates may be attributed to differences in Active Surface Area of the filter itself.
- As with the predicate devices (F40 and F60), no cellular blood components were lost in the ultrafiltrate in the F Series Hemoconcentrators.
- The production of plasma hemoglobin (hemolysis) was equivalent for all devices studied.
- Performance data also demonstrates that the molecular weight cutoff for all devices studied is approximately 65,000 Daltons. This fact is supported by data that shows that minimal albumin was lost from the blood product and that a relatively small protein, beta-2microglobulin, was filtered with the plasma water.

CONCLUSION: Based on the information and test results provided in this premarket notification, the Fresenius F Series Hemoconcentrators and tubing sets are substantially equivalent to currently marketed hemoconcentrators.



MAY 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Virginia Singer
Regulatory Affairs Manager
Fresenius USA, Inc.
Critical Care Division
2637 Shadelands Drive
Walnut Creek, CA 94598

Re: K974584
Fresenius F-series Hemoconcentrator
Models F400, F400TS, F500, F500TS, F700
F700TS, F800, and F800TS
Dated: April 3, 1998
Received: April 7, 1998
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 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

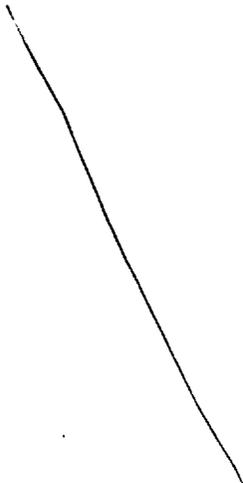
Enclosure

Indications for Use Statement

510(k) Number (if known); K974584

Device Name: Fresenius F Series 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.



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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Nalting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974584

Prescription Use
(Per 21 CFR 801.109)

OR

Over The Counter Use