

JUN 8 - 2005

Fresenius ART Hemoadsorption System
510(k) Premarket Notification
Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name: Fresenius Medical Care North America
Address: 95 Hayden Ave
Two Ledgemont Center
Lexington, MA 02420
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Fax: (781) 402-9082
Contact Person: Janet C. Kay, Senior Regulatory Affairs Specialist
Date of Preparation: February 4, 2005

B. Device Name:

Trade Name: Fresenius ART Hemoadsorption System
Common/Usual Name: Separator, Automated, Blood Cell, Diagnostic
Classification Name: Automated blood cell separator

C. Predicate Device Name:

Fresenius 2008K Dialysate Delivery System K994267
Fresenius AS104 Cell Separator, #K895435

D. Device Description/Indications for Use:

The indication for use for the Fresenius ART Hemoadsorption System is as follows:

The Art Hemoadsorption system operates and monitors the extracorporeal blood circuit to perform whole blood or plasma adsorption (when used with a commercially available plasma filter).

Brief device description

In the extracorporeal blood circuit, the blood is continuously anticoagulated with ACD-A solution. The ACD-A flow can be adjusted and is controlled in relation to the blood flow. The ACD-A flow is monitored by a drip counter.

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If a whole-blood adsorption treatment is performed, the blood pump transports blood from the inlet side of the patient's vascular access through the adsorber.

If a plasma adsorption treatment is performed, the blood pump transports blood from the inlet side of the patient's vascular access through a plasma filter. The plasma filter separates the plasma from the whole blood. The plasma pump delivers the plasma through the adsorber. The adsorber removes undesired substances from the blood or plasma.

Downstream of the adsorber, the blood or plasma flows into the bubble catcher. In case of plasma adsorption, the plasma is mixed with the blood components that have been separated in the plasma filter beforehand. The blood is then returned to the patient via the return line.

E. Substantial Equivalence:

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius ART Hemoadsorption System is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for Fresenius ART Hemoadsorption System is as follows:

Intended Use

The Art Hemoadsorption system operates and monitors the extracorporeal blood circuit to perform whole blood or plasma adsorption (when used with a commercially available plasma filter).

The intended use for the Fresenius AS104 Cell Separator is as follows:

Intended Use

The Fresenius AS104 Cell Separator is intended for use in apheresis procedures involving donors and patients.

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3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The technological characteristics of the Fresenius ART Hemoadsorption System are equivalent to those of the Fresenius 2008K and Fresenius AS104. See Table III-1 for a comparison of the components and features of the Fresenius ART Hemoadsorption and the Fresenius 2008K and AS104.

4. Does descriptive or performance information demonstrate equivalence?

- **YES** – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius ART Hemoadsorption System and demonstrates that it is substantially equivalent to the Fresenius 2008K and AS104.

F. Safety Summary

The Fresenius ART Hemoadsorption System's software validation, functional testing, and release testing rigorously tested the features of the ART machine. The results of this testing indicate that the ART Hemoadsorption System is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, training and support is provided to clinics that use the Fresenius ART Hemoadsorption System. This information promotes safe and effective use of the device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Janet C. Kay, RAC
Sr. Regulatory Affairs Specialist
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K050273
Trade/Device Name: Fresenius ART Hemoadsorption System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: April 29, 2005
Received: May 2, 2005

Dear Ms. Kay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Fresenius Medical Care

Indications for Use

510(k) Number (if known): K050273

Device Name: Fresenius ART Hemoadsorption System

Indications for Use:

The Art Hemoadsorption system operates and monitors the extracorporeal blood circuit to perform plasma adsorption (when used with a commercially available plasma separator and a PROSORBA® Immunosorba adsorption column).

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin R. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

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Fresenius Medical Care North America

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