K984586

JUN 29 1999

X. 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The contents of this 510(k) summary have been provided in conformance with 21 CFR §807.3 (*Federal Register*, Vol. 59, No. 239, Dec. 14, 1994, pg. 64295).

510(k) Summary for the
Fresenius ATR 40 and ATR 120 Autotransfusion Reservoirs

Submitter's Name and Address:	Fresenius Hemotechnology, Inc. 110 Mason Circle, Suite A Concord, CA 94520
Phone Number:	(925) 688-0990
Telefax Number:	(925) 688-0999
Contact Person:	Virginia Singer
Date Summary Prepared:	December 22, 1998
Device Trade Name:	Fresenius ATR 40 and ATR 120 Autotransfusion Reservoirs
Common name:	Autotransfusion Blood Collection Reservoir
Classification Name:	Autotransfusion Blood Collection Reservoir
Legally Marketed Devices to which substantial equivalence is claimed:	Haemonetics Cell Saver Collection Reservoir (K802674) Medtronic EL240 Blood Collection Reservoir (K915737

Intended Use: The Fresenius ATR 40 and ATR Autotransfusion Reservoirs are intended for use as autotransfusion reservoirs to collect, defoam, filter, and store blood prior to processing.

Device Features:

The Fresenius ATR 40 and ATR 120 are 3 liter blood collection reservoirs, with 40 or 120 micron filters respectively. They are used for the collection of blood lost intra- or postoperatively in surgical procedures.

Collection is performed by vacuum suction via appropriate tubing systems e.g. double lumen suction lines for aspiration and simultaneous anticoagulation or drainage adapters connected to wound drains. They are connected to the respective inlet connectors on top of the reservoir: two ¼"-connectors (one vertical, one horizontal), luer female connector and 3/8"-connector. All inlet connectors drain the fluid into a filter via a filter holder.

The ATR 40 contains a three-layer filter and the ATR 120 contains a two-layer filter that traps particulates greater than 40 and 120 microns, respectively. In both filters, the PUR foam is treated with a defoaming agent to dissolve bubbles generated in the blood collection process by mixing blood with air. Except for the filter ATR 40 and ATR 120 are identical. The filters are attached to the filter holder by a cable tie and hang like a pouch in the reservoir lumen.

The vacuum is applied via a separate vacuum line attached to a ¼" vacuum port. Positive and negative pressure level within the reservoir is limited by a pressure relief valve that opens in the range of approximately –300 mmHg and + 100 mmHg.

Up to 3 liters of aspirated blood can pass through the filter and be stored in the reservoir lumen at one time. The volume of collected blood can be controlled by calibration marks on both sides of the reservoir; the calibration marks are in increments of 100 ml from 100 ml to 3000 ml. Collected blood can be transferred to an autotransfusion device via the outlet line attached to the base of the reservoir. The flow of blood through the outlet line can be controlled with a pinch clamp. A universal adapter, compatible with ¼" male adapters and 3/8" female connectors, it attached to the distal end of the outlet line for connection to autotransfusion tubing sets. The reservoir can be attached to an IV pole using a compatible reservoir holder or the hanger on top of the reservoir.

The ATR 40 and ATR 120 Autotransfusion Devices are supplied as sterile (ETO) disposable devices with a non-pyrogenic fluid path.

Substantial Equivalence of the ATR 40

The Fresenius ATR 40 Autotransfusion Reservoir is substantially equivalent to the Medtronic EL240 Blood Collection Reservoir. The Medtronic EL240 was previously marketed under the trade name Electromedics EL40, cleared under K915737. For purposes of this discussion the Medtronic EL240 will be referred to as the "predicate device".

Technological Characteristics of the Subject Device Compared with Predicate Device

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. The answers to questions identified on this decision tree lead to a determination of substantial equivalence of the ATR 40 Autotransfusion Reservoir.

1.0 Does the New Device Have the Same Indication Statements?

Yes. The Fresenius ATR 40 and the Medtronic EL240 reservoirs are collection reservoirs intended to be used during autotransfusion procedures to collect, filter, defoam and store blood; both should not be used as cardiotomy reservoirs.

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

Yes. Both reservoirs are designed for and operated by the same principles. Blood is drawn into the reservoir using a suction handpiece; vacuum applied to the reservoir aspirates the blood from the operative field into the cavity of the reservoir. The filter is capable of filtering particles greater than 40 microns in diameter. Filtered blood leaves the reservoir via an outlet port adapter at a rate established by the autotransfusion device that further processes the blood.

The materials used to manufacture the reservoir are rigid plastics that sustain sufficient negative and positive pressure to prevent implosion/explosion. The filter materials are virtually identical.

3.0 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although, the Fresenius ATR 40 and the Medtronic EL240 reservoirs are very similar, there may be differences in the design, materials used to manufacture the assemblies and in the manufacturing methods employed to build the assemblies. These differences could impact the biocompatibility, performance, structural integrity and shelf-life of the Fresenius ATR 40 Autotransfusion Reservoir.

4.0 Are Performance Data Available to Assess Equivalence?

Yes. All blood/fluid-contacting materials in the Fresenius ATR 40 have been subjected to biocompatibility testing consistent with FDA's modified ISO standards for biological evaluation of medical devices. Information pertinent to the structural integrity of the ATR 40 and shelf-life validation has been provided.

Data is provided to the Agency that demonstrates that the blood collection, filtration, defoaming, level of hemolysis produced during use, and retention of cellular components during filtration using the Fresenius ATR 40 is substantially equivalent to the Medtronic EL240. Comparative testing was performed on the Medtronic EL240, the currently marketed version of the Electromedics EL40.

5.0 Does Performance Data Demonstrate Equivalence?

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

- The Fresenius ATR 40 satisfies requirements of the AAMI/ANSI standards for autotransfusion devices with respect to structural integrity and the materials used to manufacture the disposable set are suitable for the intended use of the device,
- Shelf-life validation studies pertinent to the Fresenius ATR 40 have determined that the biocompatibility, structural integrity, packaging integrity and sterility of the Fresenius ATR 40 will be maintained for the labeled shelf-life.
- Testing demonstrated that the blood products prepared using the Fresenius ATR 40 device are of equal quality with respect to filtration efficiency, defoaming, hemolysis, and retention of cellular components as the Medtronic EL240.

CONCLUSION: Based on the information and test results provided in this premarket notification, the Fresenius ATR 40 Autotransfusion Reservoir is substantially equivalent to the currently marketed Medtronic EL240 Blood Collection Reservoir.

Substantial Equivalence of the ATR 120

The Fresenius ATR 120 Autotransfusion Reservoir is substantially equivalent to the Haemonetics Cell Saver ® Collection Reservoir (K802674). For purposes of this discussion the Haemonetic Cell Saver ® is referred to as the "predicate device".

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. The answers to questions identified on this decision tree lead to a determination of substantial equivalence for the ATR 120 Autotransfusion Reservoir.

1.0 Does the New Device Have the Same Indication Statements?

Yes. The Fresenius ATR 120 and the Haemonetics Cell Saver ® are collection reservoirs intended to be used during autotransfusion procedures to collect, filter, defoam and store blood; neither should be used as a cardiotomy reservoir.

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

Yes. Both reservoirs and designed for are operated by the same principles. Blood is drawn into the reservoir using a suction handpiece; vacuum applied to the reservoir aspirates the blood from the operative field into the cavity of the reservoir. The filter is capable of filtering particles greater than 120 microns in diameter. Filtered blood leaves the reservoir via an outlet port adapter at a rate established by the autotransfusion device that further processes the blood.

The materials used to manufacture the reservoir are rigid plastics that sustain sufficient negative and positive pressure to prevent implosion/explosion. The filter materials are virtually identical.

3.0 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although, the Fresenius ATR 120 and the Haemonetics Cell Saver ® reservoirs are very similar, there may be differences in the design, materials used to manufacture the assemblies and in the manufacturing methods employed to build the assemblies. These differences could impact the biocompatibility, performance, structural integrity and shelf-life of the Fresenius ATR 120 Autotransfusion Reservoir.

4.0 Are Performance Data Available to Assess Equivalence?

Yes. All blood/fluid-contacting materials in the Fresenius ATR 120 have been subjected to biocompatibility testing consistent with FDA's modified ISO standards for biological evaluation of medical devices. Information pertinent to the structural integrity of the ATR 120 and shelf-life validation has been provided.

Data is provided to the Agency that demonstrates that the blood collection, filtration, defoaming, level of hemolysis produced during use, and retention of cellular components during filtration using the Fresenius ATR 120 is substantially equivalent to the Haemonetics Cell Saver ®.

5.0 Does Performance Data Demonstrate Equivalence?

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

- The Fresenius ATR 120 satisfies requirements of the AAMI/ANSI standards for autotransfusion devices with respect to structural integrity and the materials used to manufacture the disposable set are suitable for the intended use of the device,

- Shelf-life validation studies pertinent to the Fresenius ATR 120 have determined that the biocompatibility, structural integrity, packaging integrity and sterility of the Fresenius ATR 120 will be maintained for the labeled shelf-life.

- Testing demonstrated that the blood products prepared using the Fresenius ATR 120 device are of equal quality with respect to filtration efficiency, defoaming, hemolysis, and retention of cellular components as the Haemonetics Cell Saver ®.

CONCLUSION: Based on the information and test results provided in this premarket notification, The Fresenius ATR 120 Autotransfusion Reservoir is substantially equivalent to the Haemonetics Cell Saver ® Collection Reservoir.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

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

Re: K984586
Fresenius ATR 40 and ATR 120 Autotransfusion Reservoirs
Regulatory Class: II (Two)
Product Code: DTN
Dated: May 14, 1999
Received: May 17, 1999

Dear Ms. Singer:

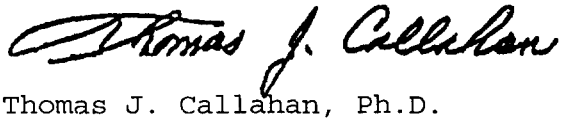
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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" (21CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known); K984586

Device Name: Fresenius ATR 40 and ATR 120 Autotransfusion Reservoirs

Indications for Use: The ATR 40 and ATR 120 Autotransfusion Reservoirs are indicated as autotransfusion reservoirs to collect, defoam, filter, and store blood prior to processing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984586

Prescription Use ✓ **OR** **Over The Counter Use** _____
(Per 21 CFR 801.109)