JUL 23 2001

K012178

510(k) Summary for the Fresenius Modified C.A.T.S Continuous Autotransfusion System AT1 Autotransfusion Set Plasma Sequestration Set Plasma Sequestration Direct Draw Set

Submitter's Name and Address:	Fresenius HemoCare, Inc. 6675 185th Ave. NE Redmond, WA 98052
Telephone Number: **Fax Number:** **Contact Person:**	425-497-1197 425-497-0397 Tom Trotter Director, Regulatory Affairs/Quality Assurance
Date Summary Prepared	11 July 2001
Device Trade Name:	Fresenius AT1 Autotransfusion Set Fresenius Plasma Sequestration Set Fresenius Plasma Sequestration Direct Draw Set
Common Name:	AT1 Autotransfusion Set Plasma Sequestration Set Plasma Sequestration Direct Draw Set
Classification Name:	Autotransfusion Apparatus (21 CFR 868.5830)
Substantial Equivalence:	The modified device is substantially equivalent to the Fresenius C.A.T.S Continuous Autotransfusion System AT1 Autotransfusion Set currently marketed. The modified device is substantially equivalent to the Fresenius C.A.T.S Continuous Autotransfusion System Plasma Sequestration Set currently marketed The modified device is substantially equivalent to the Fresenius C.A.T.S Continuous Autotransfusion System Plasma Sequestration Direct Draw Set currently marketed

Device Description	The AT1 Autotransfusion Set includes the blood-washing chamber, adapters for mounting the set into the C.A.T.S. device, blood inlet line with stepped adapter, fluid lines; and the waste and reinfusion bags. The Plasma Sequestration Set (PSQ) includes the bags required for collection of plasma and platelet rich plasma and the lines/connectors for connection to the whole blood bag and connection to the AT1 Autotransfusion Set. The Plasma Sequestration Direct Draw Set (PSQ-DD) includes all the components included in the standard PSQ Set and additionally, a blood drawing/anticoagulant line assembly.
Intended Use:	The C.A.T.S Continuous Autotransfusion System device is an autotransfusion device for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it can be used for perioperative separation of blood into Pack Red Cells (PRC), Plasma (PLS) and Platelet Rich Plasma (PRP).
Technological Characteristics:	The proposed devices have the same technological characteristics and the same basic designs and configurations as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2001

Mr. Tom Trotter
Director, Regulatory Affairs/Quality Assurance
Fresenius Hemotechnology, Inc.
6675 185th Avenue N.E., Suite 100
Redmond, WA 98052

Re: K012178
Fresenius C.A.T.S; ATI Autotransfusion Set
Regulation Number: 868.5830
Regulatory Class: II
Product Code: CAC
Dated: July 11, 2001
Received: July 12, 2001

Dear Mr. Trotter:

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) 594-4586. 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,

James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Fresenius AT1 Autotransfusion Set

Indications for Use: The Fresenius AT1 Autotransfusion Set is a component of the C.A.T.S Continuous Autotransfusion System that is an Autotranfusion device for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion.

Device Name: Fresenius Plasma Sequestration Set

Indications for Use: The Fresenius Plasma Sequestration Set is a component of the C.A.T.S Continuous Autotransfusion System that is an Autotranfusion device for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it can be used for perioperative separation of blood into Packed Red Cells (PRC), Plasma (PLS) and Platelet Reich Plasma (PRP).

Device Name: Fresenius Plasma Sequestration Direction Draw Set

Indications for Use: The Fresenius Plasma Sequestration Direction Draw Set is a component of the C.A.T.S Continuous Autotransfusion System that is an Autotranfusion device for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it can be used for perioperative separation of blood into Packed Red Cells (PRC), Plasma (PLS) and Platelet Reich Plasma (PRP).

(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 Devices
510(k) Number K012178

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