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510(k) Summary for the Fresenius C.A.T.S Autotransfusion System

Submitter's Name and Address:	Fresenius AG, Critical Care International 61343 Bad Homburg v.d.H Germany
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Contact Person:	Dr. T. Mehler
Date Summary Prepared:	March 31, 1997
Device Trade Name:	C.A.T.S Autotransfusion System
Common name:	Automated Blood Processing Autotransfusion System
Classification Name:	Autotransfusion Apparatus per 21 CFR 868.5830
Legally Marketed Device to which substantial equivalence is claimed:	Medtronic Sequestra 1000 and Haemonetics's CellSaver 5 Autotransfusion Systems

Intended Use:

The Fresenius C.A.T.S Autotransfusion System is an autotransfusion device indicated 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 whole blood into packed red cells (PRC), plasma (PLS) and platelet rich plasma (PRP).

Device Features:

The Fresenius C.A.T.S is a **continuous autotransfusion system** working on the principle of a continuous flow centrifuge. In this **continuous system**, the blood to be processed passes through a separation chamber that can be divided into several compartments in which different steps of the autotransfusion process (i.e; plasma separation, resuspension with saline and reconcentration) are performed simultaneously, creating a continuous flow of blood through the system.
The C.A.T.S device is comprised of two major components:

a) **Reusable Autotransfusion Device:** The C.A.T.S machine is an electromechanical microprocessor controlled device which incorporate the following major system

components: the user display and function keys, centrifuge housing, centrifuge rotors; blood, packed red cell (PRC) and saline roller pumps; blood, saline and PRC sensors; leakage detector, and power supply unit. Additionally, the system includes the electronic components and system software which control and monitor the blood processing procedure.

b) **Disposable AT1 Autotransfusion Set:** This disposable set incorporates the continuous washing chamber, adapters for mounting the set into the C.A.T.S device, blood inlet line with stepped adapter, pump tubing, fluid lines; and the waste and reinfusion bags.

In order to perform plasma sequestration procedures a second disposable set is necessary:

c) **PSQ Set**: a single use, disposable set, includes bags for collection of plasma and platelet concentrates. Additionally, the PSQ Set includes lines/connections for connection to the whole blood bag and connection to the C.A.T.S AT1 Autotransfusion Set.

In order to perform a plasma sequestration procedure, the PSQ Set is attached to the AT1 Autotransfusion Set. The blood bag is then connected to the blood inlet line of the PSQ Set. Separation/processing is accomplished in the washing chamber of the AT1 Autotransfusion Set.

The plasma sequestration process is accomplished in four phases which are automatically controlled by the C.A.T.S system: Separation or Sequestration Phase (plasma and red blood cell separation and collection), PRC Transfer Phase (collection of residual red blood cells), PRP Transfer Phase (collection of the buffy coat containing platelets and a small volume of plasma) and Plasma Transfer Phase (recovery of the residual plasma remaining in the washing chamber). Following completion of the plasma sequestration process, the operator can either: 1) choose to sequester another unit of blood or 2) discontinue plasma sequestration, remove the PSQ Set and prepare the AT1 Autotransfusion Set for an autotransfusion procedure.

For simplicity of use, the C.A.T.S sequestration procedure has been automated as much as possible; however, between the different phases of component collection, the operator is required to open/close clamps of the respective component lines to direct the fluid flow into the appropriate component bag. This is not unique to the C.A.T.S sequestration program as other autotransfusion systems indicated for plasma sequestration also require user intervention. In fact, with some systems, such as the Haemonetic's CellSaver 5, the user must visually monitor the red blood cell/buffy coat interface, halt the sequestration process when red blood cells enter the effluent line (by pressing the EMPTY key), and open and close clamps to the respective component lines during operation. Visual monitoring of the red blood cell/buffy coat interface and manual interruption of the plasma sequestration process are not required with the C.A.T.S device.

During plasma sequestration with the C.A.T.S system, the operator may adjust the processing speed within pre-established limits. This can be done without compromising the plasma/platelet recovery rates or the quality of the fractionated components. The centrifuge speed, which is automatically controlled by the system, can not be manually adjusted by the user.

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 utilized to make a determination of substantial equivalence. 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 C.A.T.S device, Sequestra 1000 and Cell Saver 5 autotransfusion systems are indicated for the processing of autologous shed blood, collected during a variety of surgical procedures, to obtain washed packed red blood cells for reinfusion. Furthermore, all three systems allow for plasma sequestration of blood collected preoperatively in a standard anticoagulated blood bag.

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

No. Overall the C.A.T.S, Sequestra 1000 and Cell Saver 5 autotransfusion systems employ the same basic principle of separation (i.e., centrifugation), and many of the systems' components and function of these components are similar. However, the actual design of both the disposable blood processing chamber, the disposable plasma sequestration kit and the reusable hardware; and the parameters and controls of the plasma sequestration procedure differ for the C.A.T.S device compared with the predicate autotransfusion systems.

3.0 Could the New Characteristics Affect Safety or Effectiveness?

Yes. Dissimilarities in design, materials and processing parameters between the C.A.T.S device and the two predicate autotransfusion systems could potentially affect both the safety and effectiveness of the C.A.T.S plasma sequestration program. Issues of concern would be: blood compatibility, red cell, platelet and plasma recovery rates, and resulting quality of the separated blood products. Furthermore, differences in the system electronics and associated software require validation for demonstration of proper performance.

4.0 Do the New Characteristics Raise New Types of Safety or Effectiveness Questions.

No. When used as indicated, the plasma sequestration process of the C.A.T.S Autotransfusion System does not raise questions concerning safety and effectiveness that are not also associated with the predicate devices. Issues of blood compatibility, efficiency of component recovery, quality of separated blood products and proper electronics/software function are characteristic of all automated blood processing autotransfusion devices employed for plasma sequestration.

5.0 Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

Yes. Accepted scientific methods exist for the assessment of: 1) product/processing efficiency with respect to red blood cell, platelet and plasma recovery rates, and 2) quality of the sequestered products. Furthermore, industry standards and, specifically, FDA guidances are available with respect to evaluation of biocompatibility of materials and demonstration of proper software performance.

6.0 Are Performance Data Available to Assess Effects of New Characteristics?

Yes. Studies have been undertaken to assess the new characteristics inherent in the plasma sequestration program of the C.A.T.S autotransfusion system.

Studies comparing the performance of the C.A.T.S device to one of the predicate devices, the Sequestra 1000, has been performed; additionally, in vitro blood quality testing has evaluated the safety and effectiveness of the plasma sequestration process parameters provided by the C.A.T.S system. All blood/fluid contacting materials of the PSQ Set 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 PSQ set and shelf-life validation have been provided. Furthermore, the plasma sequestration module of the C.A.T.S system software has undergone testing to assure that system software requirements are met.

7.0 Does Performance Data Demonstrate Equivalence?

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

- The blood processing performance of the Fresenius C.A.T.S plasma sequestration program is substantially equivalent to the plasma sequestration program of the predicate device, the Medtronic Sequestra 1000 Autotransfusion System, and indeed, the products prepared using the C.A.T.S device would be suitable for reinfusion.

- The PSQ Set 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 PSQ Set have determined that the biocompatibility, structural integrity, packaging integrity and sterility of the PSQ Set will be maintained for the labeled shelf-life,

- Through system software testing, it has been established that the plasma sequestration program module incorporated into the C.A.T.S's system software will meet the requirements as set forth in the Software Requirements Specification,

CONCLUSION: Based on the information and test results provided in this premarket notification, the plasma sequestration program and disposable PSQ Set of the Fresenius C.A.T.S autotransfusion device is substantially equivalent to the plasma sequestration program and accessories of the Sequestra 1000 and Cell Saver 5 autotransfusion systems, and furthermore, the C.A.T.S autotransfusion system is safe and effective for performing plasma sequestration procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Ms. Annette M. Fagnant
MedDRA Assistance, Inc.
53 Kennedy Road
Foster, Rhode Island 02825

Re: K971274
Fresenius C.A.T.S (Continuous Autotransfusion System) Plasma Sequestration Program and PSQ Set
Regulatory Class: II (Two)
Product Code: 74 CAC
Dated: April 4, 1997
Received: April 7, 1997

Dear Ms. Fagnant:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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"dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,

Thomas J. Callahan

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

Enclosure

868.5830 Autotransfusion Apparatos
CAC II

Indications for Use Statement

510(k) Number (if known): K971274

Device Name: C.A.T.S Continuous Autotransfusion System

Indications for Use: The C.A.T.S (Continuous Autotransfusion System) by Fresenius is an autotransfusion device indicated 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 Rich 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,
and Neurological Devices
510(k) Number K971274

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