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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 C.A.T.S Autotransfusion System
Plasma Sequestration-Direct Draw Program and PSQ Set (Direct Draw)**

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

Phone Number: (510) 295-0200
Telefax Number: (510) 988-1932
Contact Person: Virginia Singer

Date Summary Prepared: August 27, 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.

There have been no modifications made to the existing C.A.T.S system hardware to allow for the plasma sequestration direct draw program. Furthermore, the plasma sequestration processing procedure is performed using the same AT1 Autotransfusion Set that were subject of previous premarket notifications reviewed and concurred by the Agency. In order to perform plasma sequestration using the direct draw method, an additional disposable set, the **PSQ Set (Direct Draw-DD)** is necessary. The PSQ Set (DD) includes all components currently included in the standard PSQ set; e.g., bags required for collection of concentrated red blood cells, plasma and platelet rich plasma; and lines for connection between the PSQ Set (DD) and AT1 Autotransfusion Set. Additionally, a blood drawing line/anticoagulant burette assembly required for blood collection and anticoagulation is included in the package. The burette drip chamber allows for manual metering of the anticoagulant during blood withdrawal.

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 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 either in a standard anticoagulated blood bag or by direct patient connection.

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

Yes. There are differences in technology and operation between the C.A.T.S device and the predicate devices. However, with the exception of the blood collection and anticoagulation method, the technological characteristics of the C.A.T.S Plasma Sequestration Direct Draw procedure are the same as that of the standard plasma sequestration procedure. Both the disposable components and the processing procedure employed for sequestration are identical.

The technological characteristics of the patient drawing and anticoagulant line of the C.A.T.S and Medtronic Sequestra are the same. The C.A.T.S and Medtronic blood withdrawal/anticoagulation subassemblies are manufactured using similar components and they are used in the same manner. Both sets must be connected to an anticoagulant source and are directly connected to the patient's venous access site. Anticoagulant is stored in the burette chamber and is manually metered to maintain a suitable anticoagulant:whole blood ratio. As stated previously, the C.A.T.S and Sequestra devices are designed to prevent fluid from being pumped back into the patient during the blood withdrawal process.

3.0 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although, the disposable assemblies of the C.A.T.S and Sequestra 1000 are very similar, there may be differences in the materials used to manufacture the assemblies and in the manufacturing methods employed to build the assemblies. These differences could impact the biocompatibility, structural integrity and shelf-life of the PSQ Set (DD). Furthermore, the C.A.T.S system software has been modified to include a new software program module for the direct draw plasma sequestration procedure. The program module requires validation to ensure proper performance.

4.0 Are Performance Data Available to Assess Equivalence?

Yes. All blood/fluid contacting materials of the PSQ Set (DD) 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 has been provided. Furthermore, the plasma sequestration direct draw program module of the C.A.T.S system software has undergone testing to assure that system software requirements are met.

5.0 Does Performance Data Demonstrate Equivalence?

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

- 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 (Direct Draw) have determined that the biocompatibility, structural integrity, packaging integrity and sterility of the PSQ Set (Direct Draw) will be maintained for the labeled shelf-life,
- Through system software testing, it has been established that the plasma sequestration direct draw 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 direct draw plasma sequestration program and disposable PSQ Set (DD) of the Fresenius C.A.T.S autotransfusion device is substantially equivalent to the currently marketed plasma sequestration program and PSQ Set. Additionally, the C.A.T.S direct draw plasma sequestration program and PSQ Set (DD) are substantially equivalent to the direct draw programs and accessories of the Sequestra 1000 and Cell Saver 5 autotransfusion systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K973378
Fresenius C.A.T.S. (Continuous Autotransfusion System)
Regulatory Class: II (Two)
Product Code: CAC
Dated: September 5, 1997
Received: September 8, 1997

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.

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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 "<http://www.fda.gov/cdrh/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): K 97 33 78

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)

Ben G. Campbell

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 973378

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____