K984233

FEB 1 1999

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

Submitter's Name and Address:	Fresenius Hemotechnology, Inc. 110 Mason Circle, Suite A Concord, CA 94520
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Contact Person:	Virginia Singer
Date Summary Prepared:	November 24, 1998
Device Trade Name:	Fresenius C.A.T.S Autotransfusion Accessories: ATS Suction Line ATY Y-Adapter ATO Oxygenator Line
Common name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Legally Marketed Device to which substantial equivalence is claimed:	Dideco-Shiley Autotransfusion Accessories (K872159)

Intended Use:

The ATS Suction Line is a suction line to aspirate and anticoagulate blood from the surgical field into an autotransfusion reservoir with ¼" suction port connected to a vacuum source.

The ATY Y-Adapter is a Y-Adapter to connect two autotransfusion reservoirs with 1/4'' female outlet connector to an autotransfusion device.

The ATO Oxygenator Line is a tubing system to connect an oxygenator with 1/4'' male connector to an autotransfusion device: - via a Y-adapter connected to an autotransfusion reservoir; or
- directly to the autotransfusion device accepting a 1/4'' female connector; or
- via an autotransfusion reservoir.

Device Features:

The ATS Suction Line consists of a double lumen tubing set for collection and anticoagulation of shed blood in surgery or trauma. The large tubing is used for aspiration of the shed blood. The small tubing welded to the large tubing provides anticoagulation. The large suction tube and small anticoagulation tube meet at the Yankauer adapter, to provide anticoagulation immediately after collection of blood. The suction line is connected to the appropriate collection reservoir by a ¼'' female connector. The anticoagulant line is spiked to a anticoagulant container. Anticoagulant dosage is controlled by a roller clamp and regulates the drip rate of the anticoagulant into the drip chamber. The Yankauer adapter is designed to adapt to suction tips from 6.5 to 9.5 mm outer diameters.

The ATY Y-Adapter is a disposable tubing set used to connect two autotransfusion reservoirs to an autotransfusion disposable set prior to processing. Each branch of the Y-Adapter may be attached to the blood outlet port of two reservoirs by 2 stepped ¼'' adapters. Each branch connecting to the reservoirs has a pinch clamp to control flow to the autotransfusion device. The Y-Adapter outlet line has a universal adapter fitting for ¼'' male connectors or 3/8'' female connectors. Alternatively, the ATY Y-Adapter can be used to connect one autotransfusion reservoir and one oxygenator line to an autotransfusion device.

The ATO oxygenator line is a disposable tubing set for the collection or transfer of shed blood from the extracorporeal circulation (ECC) in cardiac surgery to an autotransfusion reservoir or to an autotransfusion device prior to processing. The oxygenator line is connected to the coronary perfusion port of an oxygenator prior to priming ECC. After conclusion of ECC, it may be connected to the free branch of a Y-adapter attached to an autotransfusion reservoir outlet, or directly to the blood inlet line of an autotransfusion device for direct processing. Alternatively it may be connected to a ¼" inlet connector of an autotransfusion reservoir to empty the oxygenator content into the reservoir prior to processing.

All three devices are for single patient use, sterilized using ethylene oxide gas, and the fluid paths are non-pyrogenic.

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 Fresenius C.A.T.S Autotransfusion Accessories and Dideco-Shiley Autotransfusion Accessories are devices to be used during autotransfusion procedures to

- aspirate, transfer, and anticoagulate blood from the surgical field to reservoir (Suctions Line); and
- connect and transfer blood between reservoirs and/or oxygenators to an autotransfusion device (Y-Adapter) ; and
- connect and transfer blood between an oxygenator and/or reservoir to an autotransfusion device, with or without a Y Adaptor (Oxygenator Line).

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

Yes. All three devices have the same technological design. All of the devices are manufactured from polyvinyl chloride (PVC) tubing, of varying diameters, with appropriate connectors for their intended uses.

3.0 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes. As the technological design, essential dimensions, materials, and manufacturing processes of the devices are comparable, comparative performance data between the Fresenius and Dideco-Shiley devices is not needed to demonstrate substantial equivalence. Biocompatibility studies, including cytotoxicity, sensitization, intracutaneous and systemic toxicity, hemocompatibility (hemolysis), genotoxicity, and pyrogenicity testing were performed to demonstrate the compliance of the Fresenius devices with applicable standards. Structural integrity testing on aged sterilized devices was also performed to demonstrate that the Fresenius devices could withstand twice the flow capacity and negative/positive pressures associated with use of autotransfusion devices. Shelf-life studies, including seal strength and dye leakage testing, demonstrated that the packaging systems are adequate to protect the devices and maintain sterility throughout the indicated one-year shelf-life.

4.0 Does Performance Data Demonstrate Equivalence?

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

- The Fresenius C.A.T.S Autotransfusion Accessories satisfy requirements of the AAMI/ANSI standards for autotransfusion devices with respect to structural integrity and the materials used to manufacture the disposable sets and are suitable for the intended use of the device,

- Shelf-life validation studies pertinent to the Fresenius C.A.T.S Autotransfusion Accessories have determined that the biocompatibility, structural integrity, packaging integrity and sterility of the Fresenius C.A.T.S Autotransfusion Accessories will be maintained for the labeled shelf-life,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

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

Re: K984233
Fresenius C.A.T.S. Autotransfusion Accessories
Regulatory Class: II (two)
Product Code: CAC
Dated: November 24, 1998
Received: November 25, 1998

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, ²Misbranding by reference to premarket notification² (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

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); K984233

Device Name: Fresenius C.A.T.S Autotransfusion Accessories

Indications for Use:

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- directly to the autotransfusion device accepting a 1/4'' female connector; or
- via an autotransfusion reservoir.

(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 K984233

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