

NOV - 1 1999

**ABBREVIATED 510(k) SUMMARY
FOR
DIDECO ATS AUTOTRANSFUSION CARDIOTOMY RESERVOIR**

1. SPONSOR

Dideco S.P.A
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Date Prepared: August 2, 1999

2. DEVICE NAME

Proprietary Name: Dideco ATS Autotransfusion Cardiotomy Reservoir
Common/Usual Name: Autotransfusion reservoir
Classification Name: Accessory to an autotransfusion apparatus

3. PREDICATE DEVICE

Dideco-Shiley ACR-40 Autotransfusion Cardiotomy Reservoir (K884872)

4. DEVICE DESCRIPTION

The Dideco ATS Autotransfusion Cardiotomy Reservoir (Dideco ATS) is a modification of the Dideco-Shiley ACR-40 Autotransfusion Reservoir (ACR-40) (K884872). The Dideco ATS is identical in intended use and fundamental technology to the previously cleared autotransfusion reservoir. Both the proposed and predicate devices consist of a reservoir with an internal filter system.

The proposed device is available with two different means of removing fluids from the reservoir. The "draw tube configuration" has a draw tube attached to a fluid outlet port in the reservoir cover. Fluids may also be drained from this version of

the reservoir via a piercable connector at the bottom of the reservoir housing. In the second form of the device, the "bottom outlet" version, the fluid outlet port is located on the bottom of the housing.

In both configurations of the device, fluids enter the reservoir through an inlet port in the reservoir cover which is connected to the internal filter system. There is also a Luer lock connector on the reservoir cover which bypasses the filter system. Both versions of the reservoir also contain an overflow valve to prevent the volume of fluid in the reservoir from exceeding the maximum holding capacity.

5. INTENDED USE

The Dideco ATS is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Dideco ATS is modified from the Dideco-Shiley ACR-40 as follows:

- increased holding capacity of the reservoir
- addition of a second configuration with the outlet port on the bottom of the reservoir housing
- elimination of the need for a reusable outer shell
- modification of the support system for the filter assembly

7. PERFORMANCE TESTING

Biocompatibility testing was performed to meet the requirements of ISO 10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" for an external communicating device in limited (<24 hrs.) contact with circulating blood. Test results confirm that the device is biocompatible for its intended use. Additional biological testing demonstrated that the finished device is nonpyrogenic, sterile, and had ETO sterilization residuals within specification.

Summary of Performance Testing Conducted on the Dideco ATS

Test	Results
Hemolysis and Cell Depletion	The design modifications incorporated into the proposed Dideco ATS did not cause a depletion in platelet or white blood cell populations. No change in hematocrit or total plasma hemoglobin was observed after six hours recirculation.
Reservoir Housing Integrity	The Dideco ATS reservoir maintained its physical integrity when pressurized to 1.5 times the maximum expected clinical operating levels without exhibiting any leakage or structural damage.
Breakthrough Time and Volume	The modifications to the filter assembly incorporated into the proposed Dideco ATS did not affect the time or volume of blood required to penetrate the filter material and enter the reservoir housing.
Residual Volume	The residual volumes of the Dideco ATS are comparable to the predicate Dideco-Shiley ACR 40.
Filtration Efficiency	The Dideco ATS had a filtration efficiency comparable to that of the ACR 40 in the size range of 40 microns or larger specified in the Instructions for Use.
Connector Pull Strength	The integrity of the connections in the Dideco ATS is sufficient to withstand a pull force of 50 Newton for 15 seconds..
Shelf Life	Test results support a five-year shelf life for the Dideco ATS reservoir.

The results of the biological and performance testing demonstrate that the proposed Dideco ATS is substantially equivalent to the Dideco-Shiley ACR-40 and is safe for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynthia J.M. Nolte, Ph.D.
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K992599
Dideco ATS Autotransfusion Cardiomy Reservoir
Regulatory Class: II (Two)
Product Code: 74 DTN
Dated: August 2, 1999
Received: August 3, 1999

Dear Dr. Nolte:

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.

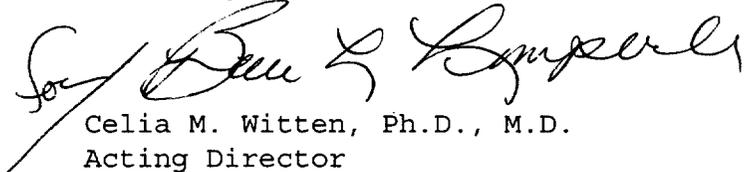
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Cynthia J.M. Nolte, Ph.D.

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,



Celia M. Witten, Ph.D., M.D.
Acting Director

Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992599

Device Name: Dideco ATS Autotransfusion Cardiotomy Reservoir

Indications For Use:

The Dideco ATS Autotransfusion Cardiotomy Reservoir is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K992599

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____