XIV. 510(k) SUMMARY

A. Name and Address of Submitter

Sorin Biomedical Inc.
17600 Gillette Avenue
P.O. Box 19503
Irvine, California 92713-9503

FEB 20 1998

B. Telephone and Fax Numbers of Submitter

Telephone: (714) 250-8322
Fax: (714) 757-8644

C. Name of Contact Person

Susan Reimers
Manager, Clinical and Regulatory Affairs

D. Date Summary was Prepared: September 16, 1996

E. Device Name

Trade or Proprietary Name:

Dideco Compact-A Autotransfusion System

Common Name:

Autotransfusion Apparatus

Classification Name:

Autrotransfusion Devices

F. Summary of Substantial Equivalence

The Blood Component Collection set is substantially equivalent in intended use, materials, design, and performance characteristics to the Electromedics Plasma Sequestration Set.

G. Device Description

The Blood Components Collection Set consists of a four-way adapter, a bag spike assembly, and two (2) collection bags. The four way adapter is inserted between the wash bowl and waste bag components of a preassembled surgical wash. The collection bags are attached to the free arms of the adapter. Whole blood to be processed may be collected in the immediate preoperative period into a transfer bag, which is then attached to the inlet side of the wash set using the bag spike assembly. In addition, blood may be collected directly from the patient by utilization of a filtered burette assembly intended for the administration of anticoagulation solution during preoperative collection of patient blood for sequestration of PRP/PPP. Alternately, whole blood from the extracorporeal circuit (e.g. cardiotomy reservoir or oxygenator) may be processed during the intraoperative period in the same manner.

H. Device Intended Use

Code 150 Blood Component Collection Set is intended for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected into transfer bags.

Code 151 Blood Component Collection Set with Direct Draw Line is intended for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected directly from the patient.

The process of PRP/PPP is to be performed in the immediate preoperative period, prior to the surgical procedure and before the establishment of cardiopulmonary bypass. The collected PRP/PPP shall be administered during or after the operation to aid in the normalization of the patient's hemocoagulative state.

I. Summary of Comparison of Technological Characteristics

The technological characteristics of the Blood Component Collection sets are similar to the Electromedics Plasma Sequestration Set. Both sets are identical in respect to their process steps, method of operation, materials, and suggested flow rates. They are both indicated for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected from the patient.

J. Summary of Nonclinical Tests

Substantial equivalence was based on a comparison of test results from the following *in vitro* physical and functional tests:

Physical Tests

Pull Testing

Pull testing was performed to ensure the blood components collection set can be securely attached to the preassembled surgical wash set to prevent being inadvertently disconnected. The results of the physical testing demonstrate that a secure connection can be established between the blood components collection set and the reassembled surgical wash set.

Volume Accuracy

The purpose of this test was to verify the accuracy of the volume label on the burette assembly by recording the volume indication at specific volume levels. All burettes recorded accurately at the specified volumes.

Leak Testing of the Filtered Burette

Leak testing was conducted on the blood component burette assembly under pressure. Each unit was slowly pressurized to 15 ± 0.5 psi and submerged under water.

Biocompatibility

Biocompatibility testing was performed on finished, sterilized devices in accordance with Tripartite Guidances for the category of " externally communicating devices, blood path direct: with a short term contact duration (5 minutes to 29 days) ". Results demonstrate that the blood contacting components of the Blood Component Collection Set are safe for their intended use.

K. Conclusions

Based upon the above information, Sorin Biomedical Inc. concludes that the blood component collection set is substantially equivalent to the Electromedics AT-1000 Sequestration Set for the plasma sequestration indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1998

Ms. Sharon Thompson
Director, Regulatory Affairs/Quality
Sorin Biomedical, Inc.
17600 Gillette Avenue
P.O. Box 19503
Irvine, CA 92713-9503

Re: K963758
Code 150 Blood Component Collection Set
Code 151 Blood Component Collection Set with Direct Draw Line
Regulatory Class: II (two)
Product Code: 74 CAC
Dated: January 30, 1998
Received: February 2, 1998

Dear Ms. Thompson:

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.

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

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

Enclosure

510(k) Number (if known): K963758

DUPLICATE

Device Name: CODE 150 BLOOD COMPONENT COLLECTION SET AND WITH DIRECT DRAW LINE

Indications For Use:

Code 150 Blood Component Collection Set is intended for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected into transfer bags.

Code 151 Blood Component Set with Direct Draw Line is intended for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected from directly the patient.

The process of PRP/PPP is to be performed in the immediate preoperative period, prior to the surgical procedure and before the establishment of cardiopulmonary bypass. The collected PRP/PPP shall be administered during or after the operation to aid in the normalization of the patient's hemocoagulative state.

The Electronmedics PRP/PPP Sequestration Kits are indicated for the same use as the Code 150 and Code 151 Blood Component Collection Sets.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K963758