

14963759

FEB 20 1998

**XIV. 510(k) SUMMARY**

**A. Name and Address of Submitter**

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

**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 and Compact-M Autotransfusion Systems

*Common Name:*

Autotransfusion Apparatus

*Classification Name:*

Autotransfusion Devices

**F. Summary of Substantial Equivalence**

The Dideco Compact-A and Compact-M Autotransfusion Systems are substantially equivalent in intended use, materials, design, and performance characteristics to the Electromedics AT-1000.

### **G. Device Description**

The Dideco Compact-A and Compact-M Autotransfusion Systems are composed of the following equipment: a high-speed lightweight automatic autotransfusion system including a rolling cart for the system with an IV pole and a portable vacuum pump module.

### **H. Device Intended Use**

The Dideco Compact-A and Compact-M Autotransfusion Systems are intended to process, shed or collect blood for autologous transfusion. The Compact-A and Compact-M Autotransfusion Systems are to be used with disposables for the collection of shed blood and aspirated body fluids, and the separation of erythrocytes from other components of the aspirated blood prior to, during and/or after a surgical procedure. The Systems are also recommended to collect platelet-rich plasma (PRP) and/or platelet-poor plasma (PPP) from the patient's whole blood immediately preoperative or intraoperative to a surgical procedure.

### **I. Summary of Comparison of Technological Characteristics**

The technological characteristics of the Dideco Compact-A and Compact-M Autotransfusion Systems are similar to the Electromedics AT-1000 System. All three (3) systems are identical in respect to their process steps, method of operation, materials, and suggested flow rates. All three (3) are indicated for separation of Platelet-Poor Plasma (PPP) and Platelet-Rich Plasma (PRP) from whole blood collected from the patient.

### **J. Summary of *In-Vivo* Tests**

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

- plasma free Hgb, ADP/Collagen and pH testing
- cell and platelet counting.

### **K. Conclusions**

Based upon the above information, Sorin Biomedical Inc. concludes that both the Dideco Compact-A and Compact-M Autotransfusion Systems and predicate Electromedics AT-1000 Autotransfusion System have comparable and acceptable performance for the indication of the collection of shed blood and aspirated body fluids, and the separation of erythrocytes from other components of the aspirated blood prior to, during and/or after a surgical procedure. The systems are also indicated for use to collect platelet-rich plasma (PRP) and/or platelet-poor plasma (PPP) from the patient's whole blood immediately preoperative or intraoperative to a surgical procedure.



FEB 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K963759  
Dideco Compact and Compact A Autotransfusion Systems  
Regulatory Class: II (two)  
Product Code: 74 CAC  
Dated: January 30, 1998  
Received: February 4, 1998

Dear Ms. Thompson:

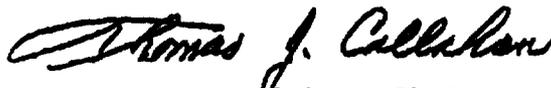
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K963759/A1

510(k) Number (if known): K963759

Device Name: DIDECO COMPACT-A AND COMPACT-M AUTOTRANSFUSION SYSTEMS

Indications For Use:

The Dideco Compact-A and Compact-M Autotransfusion Systems are intended to process, shed or collect blood for autologous transfusion. The Compact-A and Compact-M autotransfusion systems are to be used with disposables for the collection of shed blood and aspirated body fluids, and the separation of erythrocytes from other components of the aspirated blood prior to, during and/or after a surgical procedure. The systems are also recommended to collect platelet-rich plasma (PRP) and/or platelet-poor plasma (PPP) from the patient's whole blood immediately preoperative to a surgical procedure.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

*Lee A. Campbell*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K963759