

DEC 16 1998

K982650

**APPENDIX H**

**510(k) Summary**

**510(k) Summary**  
**Dideco S.p.A. Autologous Blood Management System**  
*(per 21 CFR 807.92)*

**1. SPONSOR/APPLICANT**

Contact: Mr. Luigi Vecchi  
Dideco, S.p.A.  
via Statale 12 Nord, 86  
I-41037 Mirandola (MO), Italy  
Telephone: 011 39 535 298 11  
Facsimile: 011 39 535 252 29

**2. DEVICE NAME**

Proprietary Name: Autologous Blood Management System (ABMS)  
Common/Usual Name: Autotransfusion Device  
Classification Names: Autotransfusion Apparatus

**3. PREDICATE DEVICES**

- STAT-P K884564
- Compact K910991 (*under the name Shiley Therapeutic Autotransfusion System*)
- Compact-A K940519  
K963758  
K963759
- AT-1000 K Number could not be identified

**4. INTENDED USE**

The ABMS is indicated for intraoperative and postoperative recovery of blood, washing of the processed blood, and pre-operative sequestration (with indirect and direct patient connection). Typical clinical applications of autotransfusion include the following surgical specialties: Cardiovascular, Orthopedics, Thoracic, Transplant Surgery, Emergency (Trauma), Neurosurgery, Obstetrics and Gynecology, and Urology.

**5. DEVICE DESCRIPTION**

The ABMS consists of hardware and disposables. It is an enhancement of the parent device, the Dideco Compact-A. It integrates the automated autotransfusion protocols of the STAT-P as well as adding automated sequestration protocols. The main elements of the hardware include the centrifuge, blood pump, three automatic clamps, control sensors, and a user interface (control panel). The modifications to the disposables are an increase in the thickness of the base of the bowl and a change in labeling to the new product codes.

**6. BASIS FOR DETERMINATION OF EQUIVALENCE**

Dideco S.p.A. makes the claim of substantial equivalence based on the intended use, indications for use, design, operational and technological characteristics, materials of construction, and principles of operation.

Bench and electrical (safety and EMI/EMC) testing presented in this 510(k) demonstrates that the ABMS is substantially equivalent to the Compact-A in these areas. In addition, a clinical study was conducted to compare the results obtained using automated sequestration (ABMS) with those previously submitted to FDA for the manual sequestration process. As shown in Table H-1 below, results for the PRP collected with the ABMS in the automatic mode were similar to those using the manual mode. The lower standard deviations for the ABMS results demonstrate more consistency and overall reproducibility in product collection than that observed with the manual sequestration process.

Table H-1. Sequestration Results

Characteristic		ABMS	Manual Process
PRP Platelet Yield ( $10^{11}$ )	Mean	0.79	0.75
	SD	0.29	0.32
PRP Platelet Collection Efficiency (%)	Mean	69.2	69.4
	SD	17.6	20.3

A side by side comparison of the characteristics of the ABMS with cited predicate devices is provided in Table H-2.

Table H-2. Comparison of the ABMS with Predicate Devices

Characteristic	ABMS	STAT-P	COMPACT	COMPACT-A	AT-1000
Separation by centrifugation	YES	YES	YES	YES	YES
Separation chamber: bowl	YES	YES	YES	YES	YES
Available bowl sizes (ml)	55, 125, 175, 225	55, 125, 175, 225	55, 125, 175, 225	55, 125, 175, 225	125, 225, 375
Blood source for PPP/PRP	bag or patient	NA	bag or patient	bag or patient	bag or patient
Fully and semi-automatic processing	YES	YES	NO	YES	YES
Air detector	YES	YES	YES	YES	YES
Buffy coat detector	YES	YES	YES	YES	YES
Pre-programmable	YES	YES	NO	YES	YES
Reprogrammable	YES	YES	NO	YES	YES
Tools required for bowl installation	NO	YES	NO	NO	YES
Integral vacuum unit	NO	YES	NO	NO	YES
Dimensions (inches)	17 x 22 x 18	34 x 20 x 31	17 x 22 x 18	17 x 22 x 18	17 x 31 x 48
Weight (approx. in lbs.)	73	262	73	73	265
Identical tubing diameter	YES	YES	YES	YES	YES
Blood pump speed (range in ml/min)	25-1000	25-1000	25-1000	25-1000	0-1000
Centrifuge speed (range in RPM)	1500-5600	1500-4800	1500-5600	1500-5600	2400-5600
PPP collection parameters	50 ml/min 5600 RPM	NA	50 ml/min 5600 RPM	50 ml/min 5600 RPM	50-100 ml/min 5600 RPM
PRP collection parameters	50 ml/min 2400 RPM	NA	50 ml/min 2400 RPM	50 ml/min 2400 RPM	50-100 ml/min 2400 RPM
<b>Operating Phases</b>					
PRIME mode	YES	YES	YES	YES	YES
WASH mode	YES	YES	YES	YES	YES
EMPTY mode	YES	YES	YES	YES	YES
RETURN mode	YES	YES	YES	YES	YES
CONCentrate mode	YES	YES	YES	YES	YES
CONTInuous operation	YES	YES	YES	YES	YES
BQW (Better Quality Wash feature)	YES	NO	YES	YES	YES (Pulse Wash Mode)



DEC 16 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dideco, S.P.A.  
c/o Ms. Rosina Robinson  
Senior Staff Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

Re: K982650  
Dideco Autologous Blood Management System (ABMS)  
Regulatory Class: II (Two)  
Product Code: CAC  
Dated: November 11, 1998  
Received: November 12, 1998

Dear Ms. Robinson:

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.

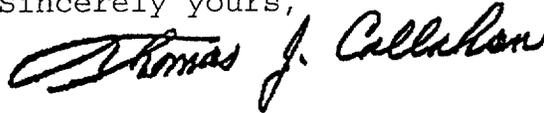
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

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

510(k) Number (if known): K 982650

Device Name: Dideco Autologous Blood Management System (ABMS)

Indications For Use:

The ABMS is indicated for intraoperative recovery of blood, washing of blood collected in the post-operative period, and pre-operative sequestration (with indirect and direct patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:

- Cardiovascular
- Orthopedics
- Thoracic
- Transplant Surgery
- Emergency (Trauma)
- Neurosurgery
- Obstetrics and gynecology
- Urology

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K 982650

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use