FEB 15 2011

5. 510 (k) Summary

Submission date	January 4th 2011
Submitter's Name **Address**	Eurosets srl Strada Statale 12, n°143 41036 Medolla (MO) Italy
Establishment Registration Number	**K102109**
Date of Summary	January 4th , 2011
Telephone Number **Fax Number**	0039 0535660334 0039 0535 51248
Contact Person	Dr. Katia Vescovini, Regulatory Affairs Manager Strada Statale 12, n°143 41036 Medolla (MO) Italy
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Trade name of the Complete Device	Advance membrane gas exchange (A.M.G.)
Trade name of the Oxygenating module	A.L.ONE A.M.G.
Trade name of the Cardiotomy reservoir	VCR 4500
Common or Usual Name of the CompleteDevice	A.M.G. advanced membrane gas exchange and accessories
Common or Usual Name of the Oxygenating module	A.M.G. Oxygenating module
Common or Usual Name of Cardiotomy reservoir	Venous cardiotomy resevoir 4500

Classification Name of the Complete Device	Cardiopulmunary device Classification Name: Advanced membrane gas exchange Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Classification Name of the Oxygenating module	Oxygenator cardiopulmonary bypass Cardiovascular Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Classification Name of Cardiotomy reservoir	Hard shell Venous/cardiotomy reservoir Cardiovascular Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Identification of the Predicate Device for the Complete Device	Proprietary Name: PRIMO2X Classification Name: OXYGENATOR, CARDIOPULMONARY BYPASS Registered Establishment Name: SORIN GROUP ITALIA S.R.L Registered Establishment Number: 9680841 Owner/Operator: SORIN GROUP ITALIA S.R.L Owner/Operator Number: 9011842 Establishment Operations: Manufacturer 510 (k): K050447 Device Name: PERFORMA ADULT HOLLOW FIBER MEMBRANE OXYGENATOR Applicant DIDECO S.R.L. 195 West St., Waltham, MA 02451
Identification of the Predicate Oxygenating module	Proprietary Name: PRIMO2X Classification Name: OXYGENATOR, CARDIOPULMONARY BYPASS Registered Establishment Name: SORIN GROUP ITALIA S.R.L Registered Establishment Number: 9680841 Owner/Operator: SORIN GROUP ITALIA S.R.L Owner/Operator Number: 9011842 Establishment Operations: Manufacturer 510 (k): K050447 Device Name: PERFORMA ADULT HOLLOW FIBER MEMBRANE OXYGENATOR Applicant DIDECO S.R.L. 195 West St., Waltham, MA 02451
Identification of the Predicate Device for the Cardiotomy	Please note that regarding the card pore size employed by the AMG, Eurosets will refer to the following predicate device: - SYNTHESIS Cardiotomy resevoir, (K073380), produced by

reservoir	the manufacturer SORIN GROUP ITALIA S.R.L.; Please also note that with regard to the membrane surface area of the AMG oxygenator, reference will be made to the following devices: - Synthesis manufactured by SORIN GROUP ITALIA S.R.L., (K073380).
Device Description of the Complete Device	The AMG Adult Hollow Fiber Oxygenator is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG oxygenating device for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass. It includes a detachable 4.5 liter blood reservoir.
Device Description of the Oxygenating module	The AMG Adult Hollow Fiber Oxygenator is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG oxygenating device for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass.
Device Description of the Cardiotomy reservoir	Hardshell Venous and Cardiotomy Reservoir
Technology comparison of the Complete Device	The A.M.G. has the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the predicate device. On the base of these comparative data the AMG Oxygenator does not introduce new or substantially modified materials or design when compared with the predicate device.
Technology comparison of the Oxygenating module	The A.L.ONE A.M.G. has the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the predicate device. On the base of these comparative data the AMG Oxygenator does not introduce new or substantially modified materials or design when compared with the predicate device.

Technology comparison of the Cardiotomy reservoir	The Hardshell Venous and Cardiotomy Reservoir has the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the predicate device. On the base of these comparative data the AMG Oxygenator does not introduce new or substantially modified materials or design when compared with the predicate device.
Intended Use of the CompleteDevice	The AMG Adult Hollow Fiber Oxygenator is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG oxygenating device for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass. It includes a detachable 4.5 liter blood reservoir. The device is used to temporarily substitute the functions of the lung as it supplies oxygen and removes carbon dioxide from the blood. A.M.G. is a single use device.
Intended Use of the Oxygenating module	A.L.ONE A.M.G. is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.
Intended Use of the Cardiotomy reservoir	VCR 4500 is intended to collect the blood from the suckers placed in the operative field during surgical treatments , and the blood coming from the patient's cave venous. VCR 4500 is an ADULT Cardiotomy reservoir. VCR 4500 should not be used for more than 6 hours.
Performance testing of the CompleteDevice, Oxygenating module and Cardiotomy reservoir	Applicable tests were carried out in accordance with the requirements of ISO 10993-1:2003 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. Tests were performed on devices accelerated aged to an equivalent of three years real time aging. Sterility, pyrogenicity. EO residuals and package integrity testing were also conducted. The results of this testing met established specifications. In vitro testing was carried out in accordance with the requirements of ISO 7199 and the Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions -

Final Guidance for Industry and FDA Staff November 13, 2000 to provide the data necessary to demonstrate compliance of the predicate device with safety and effectiveness requirements. The A.M.G. Oxygenator, A.L.ONE A.M.G. Oxygenator and Hardshell Cardiotomy Reservoir aged to 3 years was tested for gas transfer characteristics, pressure drop and plasma leakage, heat exchanger performance, hemolysis tests (blood damage), operating blood volume and mechanical integrity. The results of these tests met established specifications.

Based upon a comparison of devices and performance testing results, the A.M.G. Oxygenator, A.L.ONE A.M.G. and the Hardshell Venous Cardiotomy Reservoir are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eurosets, s.r.l.
c/o Eric J. Nemeth
55 Madison Ave., Suite 400
Morristown, New Jersey 07960

FEB 15 2011

Re: K102109
Trade Name: Eurosets Advanced Membrane Gas Exchange ("AMG")
Regulation Number: 21 CFR 870.4350
Regulation Name: Oxygenator, cardiopulmonary bypass
Regulatory Class: II
Product Code: DTZ
Dated: January 4, 2011
Received: January 7, 2011

Dear Mr. Nemeth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. 510 (k) Summary

Indications for Use

510(k) Number (if known): K102109

Device Name: Advanced Membrane Gas Exchange (AMG)

Indications for Use:

The AMG Adult Hollow Fiber Oxygenator is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

The AMG oxygenating device for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass.
It includes a detachable 4.5 liter blood reservoir.
The device is used to temporarily substitute the functions of the lung as it supplies oxygen and removes carbon dioxide from the blood.

AMG is a single use device.

Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801.109) (Part 21 CFR 801 Subpart C)

(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 Devices

510(k) Number K102109