K061031

510(k) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	April 13, 2006
DEVICE TRADE NAME:	D 100 L001 Ph.I.S.I.O: D 100 L001 Ph.I.S.I.O Newborn Hollow Fiber Oxygenator with Integrated Hardshell Cardiotomy/Venous Reservoir with phosphorylcholine coating (hereafter referred to as D 100 Ph.I.S.I.O.)
COMMON NAME:	Hollow Fiber Membrane Oxygenator with Hardshell Cardiotomy/Venous Reservoir
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator / Cardiopulmonary Bypass Heat Exchanger / Cardiopulmonary Bypass Blood Reservoir / Cardiopulmonary Bypass Defoamer
UNMODIFIED DEVICE	D 901 Lilliput 1 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with phosphorylcholine coating (open and closed system) (hereafter referred to as D 901 Ph.I.S.I.O.) (K991737, K010478).
PREDICATE DEVICE:	D 901 Lilliput 1 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with phosphorylcholine coating (open and closed system) (K991737, K010478). D 920 Lilliput 1 Twin Reservoir Ph.I.S.I.O., Hardshell Venous Cardiotomy Reservoir with phosphorylcholine coating (K001602)

JUN - 2 2006

DEVICE DESCRIPTION:

The D 100 L001 Ph.I.S.I.O Newborn Hollow Fiber Oxygenator with Integrated Hardshell Cardiotomy/Venous Reservoir with phosphorylcholine coating (hereafter referred to as the D 100 Ph.I.S.I.O) is a high efficiency microporous newborn hollow fiber membrane oxygenator integrated with an heat exchanger and connected to an hardshell cardiotomy/venous reservoir. The device is a modified version of the currently marketed D 901 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with phosphorylcholine coating unmodified device (K991737, K010478) (hereafter referred to as the D 901 Ph.I.S.I.O.). The modification is limited to an overall reduction in the size of the device, design change to the integrated heat exchanger and hardshell cardiotomy/venous reservoir and consequent updating of product specifications in the IFUs. The reduction in size enables the device to be better suited for surgical procedures on smaller pediatric patients (newborn) where a minimal priming volume is required. Other than this change the D 100 Ph.I.S.I.O. and the D 901 Ph.I.S.I.O. are identical in intended use, materials and manufacturing processes.

INDICATION FOR USE:

The D 100 L001 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with Phosphorilcholine coating is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 0.7 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation, to always assure the proper oxygenation capability of the device. The D 100 L001 Ph.I.S.I.O. should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The D 100 Ph.I.S.I.O. is similar to the D 901 Ph.I.S.I.O. unmodified device with respect to intended use, materials, biocompatibility and performance of the $PmMI_2$ coating, operating principles, control mechanisms, fundamental scientific technology and manufacturing process. The D 100 Ph.I.S.I.O. oxygenating module shares the same basic design, operating principles and control mechanisms of the D 901 Ph.I.S.I.O. module. The only modifications consist of a heat exchanger design revision with respect to D 901 Ph.I.S.I.O.. The hardshell cardiotomy/venous reservoir present in both D 100 Ph.I.S.I.O. and D 901 Ph.I.S.I.O. share the same technological characteristics, operating principles, materials except for the design. The hardshell reservoir type has been changed form a dual chamber with two distinct sections (cardiotomy and reservoir respectively) similar to the D 920 Twin Ph.I.S.I.O. to a single chamber with cardiotomy and venous section in the same chamber. These design changes

update the D 100 Ph.I.S.I.O. device with technology implemented in existing oxygenators manufactured by Sorin Group Italia S.r.l. An overall reduction of its dimensions with consequent less hollow fiber membrane material and reduced priming volume as well as some external features revision, complete the revision of the device. The D 100 Ph.I.S.I.O. is substantially equivalent to D 901 Ph.I.S.I.O. in intended use, patient population and performance specifications.

The coating of the D 100 Ph.I.S.I.O. is identical to the phosphorylcholine coating used on D 901 Ph.I.S.I.O. The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

A complete battery of 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 on the raw materials. Testing was performed on the D 901 Ph.I.S.I.O. The aged device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals. Package integrity testing was also conducted. The results of this testing met established specifications. As no new materials are used in the D 100 L001 Ph.I.S.I.O. newborn oxygenator with respect to the D 901 Ph.I.S.I.O. data collected are considered applicable to D 100 Ph.I.S.I.O. oxygenator.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 - "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 – and FDA issued on November 29, 2000 and when applicable, following the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the unmodified and predicate devices and also complying with safety and effectiveness requirements. The device aged up to 1 year was tested for gas transfer characteristics, pressure drop, plasma leakage data, heat exchanger performance evaluation, in vitro hemolysis/cell depletion, operating blood volumes, structural integrity, mechanical integrity, venous cardiotomy reservoir characterization (including breakthrough times and volumes, hold up, reservoir graduated scale accuracy, residual blood volume, defoaming capacity, filtration efficiency, microembolic activity and reservoir housing integrity) and flaking and leaching studies characterization. The results of these tests met established specifications. For comparative purposes all tests, when applicable, were carried out on sterilized aged devices comparing the D 100 Ph.I.S.I.O. and D 901 Ph.I.S.I.O. The result of the study showed that D 100 Ph.I.S.I.O. was slightly different to D 901 Ph.I.S.I.O. D 100 Ph.I.S.I.O. is smaller in overall size, has a

more packed design, and contains a different heat exchanger/reservoir design than D 901 Ph.I.S.I.O., therefore these results were expected.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the design modification affect the D 100 Ph.I.S.I.O. performance with respect to the relevant functional parameters as compared to the D 901 Ph.I.S.I.O. unmodified device. However, the results are expected because the D 100 Ph.I.S.I.O. is smaller in overall size, has a more packed design, and contains a different heat exchanger/reservoir design as compared to the unmodified device. Although these design differences affect the above performance parameters, they are intended to make the D 100 Ph.I.S.I.O. more suitable for use on newborn patients than the unmodified and predicate devices, The smaller size offers theoretical advantages in terms of reduced priming volume and consequently less hemodilution. A lower priming volume is desirable as it results in advantageous patient hemodynamic, reduced exposure of the blood cells and plasma proteins to large surface areas and reduced need of transfusion which has potential risk of donor transmitted disease.

Furthermore, the D 100 Ph.I.S.I.O. performs in a manner substantially equivalent to the D 901 Ph.I.S.I.O. with respect to biocompatibility according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Sorin Group Italla S.R.L.
c/o Mr. Parry Sall
Principal Consultant
Parexel Consulting
200 West Street
Waltham, MA 02451-1163

Re: K061031
D 100 L001 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir with phosphorylcholine coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: May 23, 2006
Received: May 24, 2006

Dear Mr. Sall:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): _____

Device Name: D 100 L001 Ph.I.S.I.O. Newborn Hollow Fiber Membrane Oxygenator with Phosphorilcholine Coating

Indications for Use:

The D 100 L001 Ph.I.S.I.O. Newborn-Hollow Fiber Membrane Oxygenator with Phosphorilcholine Coating is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 0.7 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation, to always assure the proper oxygenation capability of the device. The D 100 L001 Ph.I.S.I.O. should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K040031

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)