DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 06, 2015

Sorin Group Italia S.r.l.
% Barry Sall
Principal Consultant
Parexel Consulting LLC
195 West Street
Waltham, Massachusetts 02451

Re: K151713
Trade/Device Name: Lillipup PMP, Lilliput PMP Integrated
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: October 7, 2015
Received: October 8, 2015

Dear Barry 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151713

Device Name
Lilliput PMP
Lilliput PMP Integrated

Indications for Use *(Describe)*

Patient Population: Infants not exceeding 20 Kg (44 lb)

The device is intended for use in infants not exceeding 20 Kg (44 lb) who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous 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 during normal operation, to always assure the proper oxygenation capability of the device. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SUBMITTER: Sorin Group Italia
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41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Phone: 39 0535 29811
Fax: 39 0535 25229

DATE PREPARED: June 24, 2015

DEVICE TRADE NAMES: Lilliput PMP
Lilliput PMP Integrated

COMMON NAMES: Hollow Fiber Oxygenator
Hollow Fiber Oxygenator/Reservoir

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator/
Cardiopulmonary Bypass Heat Exchanger/
Cardiopulmonary Bypass Blood Reservoir/
Cardiopulmonary Bypass Defoamer

CLASSIFICATION CODE: DTZ

REGULATION NUMBER: 870.4350

PREDICATE DEVICE(S): D902 Lilliput Ph.I.S.I.O. (K001021)

DEVICE DESCRIPTION:

The Lilliput PMP is a high efficiency hollow fiber diffusion membrane oxygenator with integrated heat exchanger.
The device provides oxygenation and carbon dioxide removal from patient's blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia, or aids in the maintenance of normothermia during surgery.

The device can be operated at flow rates up to 2.3 liters per minute (l/min).

The Lilliput PMP is a modified version of the currently marketed D902 Lilliput Ph.I.S.I.O.

The device is offered as a standalone oxygenator module (Lilliput PMP). Similar to the predicate device, the oxygenator module can be connected with, but not limited to, the Venomidicard reservoir (K941215). This combined configuration (oxygenator module connected with the reservoir) is labeled as Lilliput PMP Integrated.

INDICATION FOR USE:

As for the predicate device the indication for use covers both configurations (Lilliput PMP and Lilliput PMP Integrated) and is the following:

The device is intended for use in infants not exceeding 20 Kg (44 lb) who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous 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 during normal operation, to always assure the proper oxygenation capability of the device. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The PMP devices have the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate device.
The PMP devices include a different oxygenating fiber consisting of polymethylpentene (PMP, surface area approx. 0.80 m^2) rather than the polypropylene fiber (PP, surface area approx. 0.64 m^2) used for the predicate device. As a result, the static priming volume is ≤140 ml rather than ≤155 ml.

No other changes have been made to the device. The reservoir has not been modified and is not subject of the present 510(k).

Except for the change of the oxygenating fiber, the PMP devices utilize the same materials as the predicate device.

No change to the intended use has been made as a result of these modifications.

The devices are substantially equivalent to the predicate device on the basis of operating principles and basic function.

There are no differences in packaging design with respect to the predicate device.

The PMP devices are ethylene oxide sterilized and have a non-pyrogenic fluid path. They are for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1.
The current draft Guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and its guidelines was also considered limited to external communicating device, circulating blood, limited contact duration.

IN VITRO TEST RESULTS:

In vitro testing was conducted on the Lilliput PMP only since the oxygenating module is the single device element subject to modifications with respect to the predicate device. The tests were performed to demonstrate predicate device substantial equivalency and compliance to safety and effectiveness requirements.
The tests were conducted in accordance with the relevant requirements of “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000”.
For the reservoir, the performance data previously submitted and already cleared are cross referenced.
The following table lists the performance tests conducted to demonstrate compliance of Lilliput PMP to the product’s performance specifications and predicate device substantial equivalency. The Lilliput PMP successfully met all acceptance criteria for each of the following tests:

- Blood trauma
- Biological activity
- Leaching of coating
- Surface modification integrity
- Surface modification coverage
- Blood volume capacity
- Oxygenating performance/blood side pressure drops
- Blood, water, gas pathway integrity
- Plasma leakage

CONCLUSIONS:

The results of in vitro studies demonstrated that the modified device performs in a manner substantially equivalent to the predicate device with respect to the relevant functional parameters.

Test results of this study demonstrate the predicate device substantial equivalence with respect to device function.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.