June 10, 2023

Sorin Group Italia S.R.L.
Luigi Vecchi
Director, Regulatory Affairs
Via Statale 12 Nord, 86
Mirandola, Modena 41037
Italy

Re: K223361
Trade/Device Name: BMR 1900 PHISIO Closed Venous Reservoir Bag
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: May 17, 2023
Received: May 17, 2023

Dear Luigi Vecchi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eric E. Richardson -S Digitally signed by Eric E. Richardson -S
Date: 2023.06.10 09:46:41 -04'00'

for Kathleen Grunder
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223361

Device Name
BMR 1900 PHISIO Closed Venous Reservoir Bag

Indications for Use *(Describe)*
The BMR1900 PHISIO Closed Venous Reservoir Bag is intended to be used in cardiopulmonary bypass procedures for periods of up to six hours.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K223361

I. Applicant Information

APPLICANT:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: +39 0535 29957 **e-mail:** luigi.vecchi@livanova.com
APPLICATION CORRESPONDANT:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: +39 0535 29957 **e-mail:** luigi.vecchi@livanova.com
DATE PREPARED:	October 1st 2022

II. Subject Devices Identification

PROPRIETARY NAME:	BMR 1900 PHISIO Closed Venous Reservoir Bag
COMMON/ USUAL NAME:	BMR 1900 PHISIO
CLASSIFICATION NAME:	Reservoir, Blood, Cardiopulmonary Bypass
REGULATION NUMBER:	21 CFR 870.4400
CLASSIFICATION PRODUCT CODE:	DTN
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

III. Predicate Devices

The **BMR 1900 PHISIO Closed Venous Reservoir Bag** is substantially equivalent to the following cleared predicate device. All models have the same fundamental scientific technology and intended use

510(k) NUMBER:	K112771
PROPRIETARY NAME:	BMR 1900 PHISIO Closed Venous Reservoir Bag
COMMON/ USUAL NAME:	BMR 1900 PHISIO
CLASSIFICATION NAME:	Reservoir, Blood, Cardiopulmonary Bypass
REGULATION NUMBER:	21 CFR 870.4400
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

IV. Device Description

The **BMR1900 PHISIO** Closed Venous Reservoir Bag (hereinafter BMR1900) is a softshell, flexible, polyvinylchloride bag designed for use in cardiopulmonary bypass surgery for periods up to six hours. It is supplied sterile with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user.

As for the unmodified device, the **BMR1900 PHISIO**. is composed of the following elements:

- A collapsible bag that serves as an in-line closed venous reservoir to contain blood volume.
- An integral 105 micron polyester filter screen which is mainly intended to facilitate the removal of large air bubbles from the blood.
- A dual four-way stopcock assembly used to manually purge the air captured by the filter screen or to administrate drugs or other solutions as needed during the cardiopulmonary bypass procedure.
- A 1/2” venous blood inlet port and a 3/8” blood outlet port.
- Connectors integral to the blood inlet port that are used to measure temperature and saturation/hematocrit of the incoming blood using external monitoring equipment, as needed.

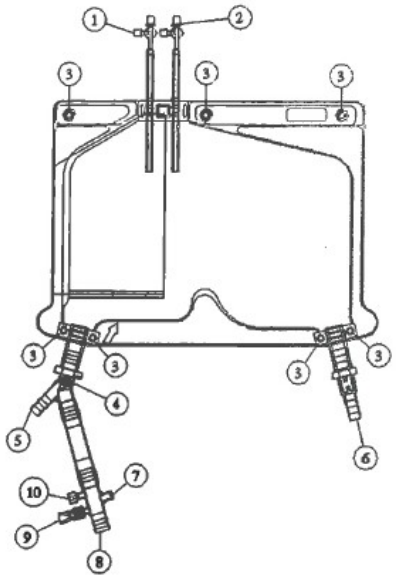
The **BMR1900 PHISIO** is designed with a 1900 mL maximum operating volume and a minimum operating volume equals to 300 mL and can be used at any flow rate up to 6 liter per minute.

The venous blood inlet/outlet ports and the dual four-way stopcock assembly are opposite located with respect to the horizontal axis: the formers are placed in the bottom of the device while the latter at the top of the bag.

Considering the vertical axis, both modified and unmodified devices present the blood inlet port with the integral cardiotomy inlet placed on one side of the bag while the blood outlet port is located on the opposite side of the bag.

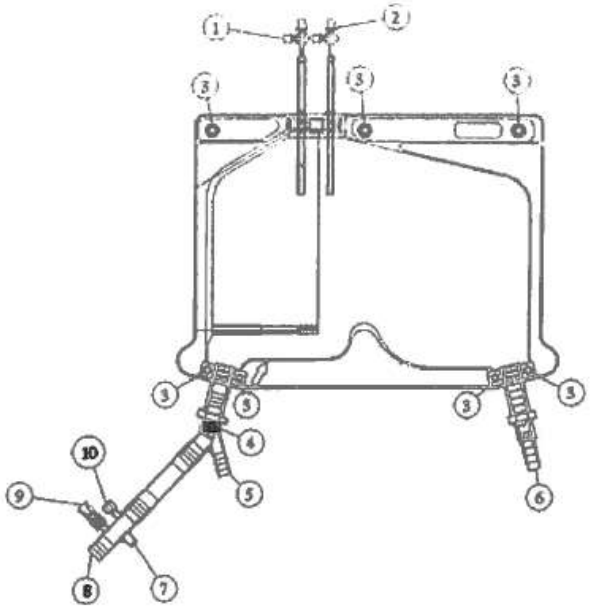
Blood enters the bag through the inlet port and passes through a polyester filter screen before exiting the bag through the outlet port. The purpose of the filter is to facilitate the removal of large air bubbles from the blood.

The **BMR1900 PHISIO** will be available with two configurations that differ only for the orientation of the venous blood inlet.
The **BMR1900 PHISIO**. has the connector of the venous blood inlet right oriented (**figure 1)** while the **BMR1900 L PHISIO**. has the connector of the venous blood inlet left oriented (**figure 2**)



1	Reservoir Vent Stopcock	6	Reservoir bag outlet
2	Auxiliary Vent Stopcock	7	SAT/HCT fitting
3	Mounting holes	8	Venous inlet
4	Auxiliary female luer lock port	9	Venous Temperature Probe fitting
5	Cardiotomy inlet	10	Venous sampling female luer lock port

Figure 1 BMR1900 PHISIO



1	Reservoir Vent Stopcock	6	Reservoir bag outlet
2	Auxiliary Vent Stopcock	7	SAT/HCT fitting
3	Mounting holes	8	Venous inlet
4	Auxiliary female luer lock port	9	Venous Temperature Probe fitting
5	Cardiotomy inlet	10	Venous sampling female luer lock port

Figure 2 BMR1900 L PHISIO

The modified device is modified version of the currently marketed **BMR1900 PH.I.S.I.O** product

V. Indications for use

The BMR1900 PHISIO Closed Venous Reservoir Bag is intended to be used in cardiopulmonary bypass procedures for periods of up to six hours.

VI. Summary of technical characteristics

The **BMR1900 PHISIO** subject device has the same principles of operation and control mechanisms as the **BMR1900 PHISIO** unmodified device. The **BMR1900 PHISIO** subject device and the **BMR1900 PHISIO** unmodified device share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. These differences are summarized below and do not raise any new issues of safety and effectiveness.

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1. The material of tubes, film and connectors is changed.
   Specifically, in the tubing the plasticizer (phthalate) and additive (polyester modified

siloxane based Tegomer® H-Si 6441) have been removed from the PVC and sub substituted with Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate(TOTM).
The PVC material of the film is changed substituting the plasticiser (phthalate) with Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate(TOTM)
The MABS of connectors is changed with a MABS without polyester modified siloxane based additive (Tegomer® H-Si 6441)

2. The Instructions for Use was revised to reflect the changes above and improve readability.

No change to the intended use has been made as a result of these modifications. Also, there are no differences in packaging type and sterilization method between **BMR1900 PHISIO** and **BMR 1900** unmodified device. Both modified and unmodified devices are for single use only, ethylene oxide sterilized and has a non-pyrogenic fluid path

VII. Substantial equivalence discussion

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the **BMR1900 PHISIO** can be deemed to be substantially equivalent to its predicate device, the unmodified **BMR1900 PHISIO** The **BMR1900 PHISIO** as designed and manufactured, does not raise new questions regarding safety and effectiveness as compared to its predicate device and is determined to be substantially equivalent to its predicate device, the unmodified **BMR1900 PHISIO**

VIII. Non clinical performance data

The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively. Applicable tests were carried out in accordance with the requirements of ISO 10993-1 standard as well as in compliance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" of September 4, 2020.
In vitro testing was performed to evaluate the impact of the different materials in the modified **BMR1900 PHISIO** version, specifically the following tests were carried on:

- Blood Path integrity
- Ease of prime
- Min/max blood volume
- Connection Integrity
- Burst test
- Surface coverage coating test
- Leaching and flacking of coating test
- Biocompatibility tests (listed and described in section 011)

This performance testing was conducted on sterile aged devices; accelerated aging for a period of time equivalent to at least 3 years as per device labeling The modified device successfully met all acceptance criteria.

The results of in vitro studies demonstrate that the subject **BMR1900 PHISIO** performs in a manner substantially equivalent to the Unmodified **BMR1900 PHISIO** predicate device with respect to the relevant functional parameters.

IX. Clinical performance data

No clinical testing was conducted in support of the **BMR1900 PHISIO**, as the indications for use are equivalent to those of their respective predicates, which have been on the market for many years. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with their respective predicates in relation to the changes subject of this submission.

X. Statement of Substantial Equivalence

As designed and manufactured and based on the intended use, technological characteristics, and performance testing, the modified **BMR1900 PHISIO** do not raise new questions regarding their safety and effectiveness as compared to their predicates devices and are determined to be substantially equivalent to the predicate devices.