August 7, 2019

Sorin Group Italia S.r.l.
℅ Scott Light
Senior Manager, Regulatory Affairs
LivaNova USA, Inc.
14401 West 65th Way
Arvada, Colorado 80004

Re: K190650
Trade/Device Name: Revolution Centrifugal Blood Pump and Revolution Centrifugal Blood Pump with PC Coating
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: January 29, 2019
Received: March 13, 2019

Dear Scott Light:

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,

Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190650

Device Name
Revolution Centrifugal Blood Pump

Indications for Use *(Describe)*

The Revolution Centrifugal Blood Pump is intended to be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of us to six hours. Refer to the console operator's manual for console operating procedures.

The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190650

Device Name
Revolution Centrifugal Blood Pump with PC Coating

Indications for Use *(Describe)*

The Revolution Centrifugal Blood Pump with PC Coating is intended to be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of us to six hours. Refer to the console operator's manual for console operating procedures.

The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

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)

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K190650

I. Applicant Information

Applicant:

SORIN GROUP ITALIA S.R.L.
Via Statale 12 Nord, 86
Mirandola (MO)
41037 Italy

Contact Person:

Luigi Vecchi
RA Director
Tel: +39-346-391-0707
e-mail: luigi.vecchi@livanova.com

Application Correspondent:

Same as Applicant

Date Prepared: August 6, 2019

II. Devices Identification

Proprietary Name:	**Revolution Centrifugal Blood Pump**
Common/Usual Name:	Nonroller-type cardiopulmonary bypass blood pump
Classification Name:	Nonroller-type blood pump
Regulation Number:	21 CFR 870.4360
Product Code:	KFM
Classification:	Class II
Classification Panel:	Cardiovascular

Proprietary Name:	**Revolution Centrifugal Blood Pump with PC Coating**
Common/Usual Name:	Nonroller-type cardiopulmonary bypass blood pump
Classification Name:	Nonroller-type blood pump
Regulation Number:	21 CFR 870.4360
Product Code:	KFM
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Devices

The **Revolution Centrifugal Blood Pump** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	**K011835**
Proprietary Name:	**Revolution Centrifugal Blood Pump**
Common/Usual Name:	Nonroller-type cardiopulmonary bypass blood pump
Classification Name:	Nonroller-type blood pump
Regulation Number:	21 CFR 870.4360
Product Code:	KFM
Classification:	Class II
Classification Panel:	Cardiovascular

The **Revolution Centrifugal Blood Pump with PC Coating** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	**K030462**
Proprietary Name:	**Revolution Centrifugal Blood Pump with PC Coating**
Common/Usual Name:	Nonroller-type cardiopulmonary bypass blood pump
Classification Name:	Nonroller-type blood pump
Regulation Number:	21 CFR 870.4360
Product Code:	KFM
Classification:	Class II
Classification Panel:	Cardiovascular

IV. Devices Description

Revolution Centrifugal Blood Pump

The Revolution Centrifugal Blood Pump is an extracorporeal blood pump that utilizes a rotating vained impeller design to move blood by centrifugal force. The device is provided sterile with a non-pyrogenic fluid pathway, and is for single use only. It is indicated for use only with a LivaNova centrifugal pump console in cardiopulmonary bypass procedures for periods of up to six hours. The device has not been qualified for long term use (greater than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

The Revolution Pump consists of a rotating vained impeller within a pump housing. The pump housing has two components, a top and bottom case, and features a central, single –barbed, 3/8” inlet port and tangential, double-barbed, 3/8” outlet port. The vained impeller is molded onto steel shaft that supports it at its axis of rotation, with the shaft rotating on a bearing at each end. The device contains a multi-pole magnet that is fully enclosed within the magnet housing and impeller, and thus does not contact the blood pathway. The magnet is designed to magnetically couple with the pump drive unit of the centrifugal pump console. Rotation of the magnet causes the impeller to rotate and pump blood via centrifugal force.

Revolution Centrifugal Blood Pump with PC Coating

The Revolution Centrifugal Blood Pump is an extracorporeal blood pump that utilizes a rotating vained impeller design to move blood by centrifugal force.

The device is provided sterile with a non-pyrogenic fluid pathway, and is for single use only. It is indicated for use only with a LivaNova centrifugal pump console in cardiopulmonary bypass procedures for periods of up to six hours. The device has not been qualified for long term use (greater than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

The Revolution Pump consists of a rotating vained impeller within a pump housing. The pump housing has two components, a top and bottom case, and features a central, single–barbed, 3/8” inlet port and tangential, double-barbed, 3/8” outlet port. The vained impeller is molded onto steel shaft that supports it at its axis of rotation, with the shaft rotating on a bearing at each end. The device contains a multi-pole magnet that is fully enclosed within the magnet housing and impeller, and thus does not contact the blood pathway. The magnet is designed to magnetically couple with the pump drive unit of the centrifugal pump console. Rotation of the magnet causes the impeller to rotate and pump blood via centrifugal force.

Blood contact surfaces of the PC coated Revolution have been coated with phosphorylcholine to improve blood compatibility, resulting in reduced platelet adhesion on the coated surfaces.

V. Indications for Use

The **Revolution Centrifugal Blood Pump** is intended to be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

The **Revolution Centrifugal Blood Pump with PC Coating** is intended for use only with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

VI. Summary of Technical Characteristics

Revolution Centrifugal Blood Pump

Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure by use of centrifugal forces.

The device contains a multi-pole magnet that is fully enclosed within the magnet housing and impeller, and thus does not contact the blood pathway. The magnet is designed to magnetically couple with the pump driver unit of LivaNova centrifugal pump consoles. Rotation of the magnet causes the impeller to rotate and pump blood via centrifugal force.

The blood flow from the Revolution Centrifugal Blood Pump responds to the resistance against which it is pumping and to the amount of fluid returned from the pump, with corresponding changes in flow and pressure. The flow is slowly accelerated from a point of relatively low tangential velocity to a maximum tangential velocity that occurs when the blood reaches the outer blade end. This unique design of the impeller vanes minimizes heat generation, hence hemolysis, while providing adequate blood flow and pressure.

These technical characteristics are identical to the predicate device, the Revolution Centrifugal Blood Pump.

Revolution Centrifugal Blood Pump with PC Coating

Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure by use of centrifugal forces.

The device contains a multi-pole magnet that is fully enclosed within the magnet housing and impeller, and thus does not contact the blood pathway. The magnet is designed to magnetically couple with the pump driver unit of LivaNova centrifugal pump consoles. Rotation of the magnet causes the impeller to rotate and pump blood via centrifugal force.

The blood flow from the Revolution Centrifugal Blood Pump with PC coating responds to the resistance against which it is pumping and to the amount of fluid returned from the pump, with corresponding changes in flow and pressure. The flow is slowly accelerated from a point of relatively low tangential velocity to a maximum tangential velocity that occurs when the blood reaches the outer blade end. This unique design of the impeller vanes minimizes heat generation, hence hemolysis, while providing adequate blood flow and pressure.

These technical characteristics are identical to the predicate device, the Revolution Centrifugal Blood Pump with PC coating.

VII. Substantial Equivalence Discussion

The following tables compare the features of the **Revolution Centrifugal Blood Pump** to its predicate the **Revolution Centrifugal Blood Pump** cleared under **K011835** and the features of the **Revolution Centrifugal Blood**

Pump with PC Coating to its predicate **Revolution Centrifugal Blood Pump with PC Coating** cleared under **K030462**, with respect to indications for use, environment of use, intended use, limitations of use, principles of operation and main performance characteristics.

Both subject devices have the same fundamental scientific technology and intended use as their respective predicate devices.

Predicate Device Comparison Table for the Revolution Centrifugal Blood Pump

Device Name	Subject Device: Revolution Centrifugal Blood Pump	Predicate Device: (K011835) Revolution Centrifugal Blood Pump	Significant Differences
Product Code	KFM	KFM	**No difference.**
Regulation #	870.4360	870.4360	
Class	II	II	
Indications for Use	The Revolution Centrifugal Blood Pump is intended to be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).	The Revolution Centrifugal Blood Pump is intended to be used with a Stockert Instrumente Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO) procedures.	**No difference.**
Environment of Use	Operating room.	Operating room.	**No difference.**
Limitations of Use/Intended Use	The pump can only be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. The pump has not been qualified through in vitro, in vivo,	The pump can only be used with a Stockert Instrumente Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. The pump has not been qualified through in vitro, in vivo,	**No difference.**

	or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO) procedures.	or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO) procedures.	
Principles of Operation	The Pump utilizes a rotating, vained impeller designed to move blood by centrifugal force.	The Pump utilizes a rotating, vained impeller designed to move blood by centrifugal force.	**No difference.**
Main Performance Features	Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure.	Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure.	**No difference.**

Predicate Device Comparison Table for the Revolution Centrifugal Blood Pump with PC Coating

Device Name	Subject Device: Revolution Centrifugal Blood Pump with PC Coating	Predicate Device: (K030462) Revolution Centrifugal Blood Pump with PC Coating	Significant Differences
Product Code	KFM	KFM	**No difference.**
Regulation #	870.4360	870.4360	
Class	II	II	
Indications for Use	The Revolution Centrifugal Blood Pump with PC Coating is intended for use only with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).	The Revolution Centrifugal Blood Pump with PC Coating is intended for use only with Stockert Instrumente Centrifugal Pump Consoles in cardiopulmonary bypass procedures for periods of up to six hours. Refer to the console operator's manual for console operating procedures. The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).	**No difference.**
Environment of Use	Operating room.	Operating room.	**No difference.**
Limitations of Use/Intended Use	The pump can only be used with a LivaNova Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. The pump has	The pump can only be used with a Stockert Instrumente Centrifugal Pump Console in cardiopulmonary bypass procedures for periods of up to six hours. The pump has	**No difference.**

	not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO) procedures.	not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO) procedures.	
Principles of Operation	The pump utilizes a rotating, vained impeller designed to move blood by centrifugal force.	The pump utilizes a rotating, vained impeller designed to move blood by centrifugal force.	**No difference.**
Main Performance Features	Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure.	Nonroller-type cardiopulmonary bypass blood pumps are designed to deliver blood at certain flow and pressure.	**No difference.**

VIII. Non-Clinical Performance Data

SORIN GROUP ITALIA S.R.L. has conducted extensive verification and validation testing of the **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating**, as centrifugal blood pumps capable of delivering blood to the patient at certain reliable flow and pressure rate. The modified component of the **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating** was tested to ensure that the systems as a whole can provide all the capabilities necessary to operate safely and effectively.

The **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating** comply with all the applicable voluntary standards related to centrifugal blood pump systems. The devices passed all the testing in accordance with national and international standards.

IX. Clinical Performance Data

No clinical testing was conducted in support of the **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating**, as the indications for use are equivalent to those of their respective predicates, which have been on the market for many years with proven safety and efficacy of use. The non-clinical testing detailed in this submission supports the substantial equivalence of these devices with their respective predicates in relation to the change subject of this submission.

X. Statement of Substantial Equivalence

Based on identical intended use and technological characteristics, as well as on identical performance testing, the **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating** can be deemed to be substantially equivalent to their predicate devices, the **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating** cleared under **K011835** and **K030462**, respectively.

The **Revolution Centrifugal Blood Pump** and **Revolution Centrifugal Blood Pump with PC Coating**, as designed and manufactured, 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.