March 15, 2018

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

Re: K180448
Trade/Device Name: INSPIRE 6M Hollow Fiber Oxygenator; INSPIRE 6F M Hollow Fiber Oxygenator with Integrated Arterial Filter; INSPIRE 8M Hollow Fiber Oxygenator; INSPIRE 8F M Hollow Fiber Oxygenator with Integrated Arterial Filter
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM ("DTM" for the "F" models only)
Dated: February 16, 2018
Received: February 13, 2018

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180448

Device Name
INSPIRE 6F M Hollow Fiber Oxygenator

Indications for Use *(Describe)*

INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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)*

K180448

Device Name
INSPIRE 6M Hollow Fiber Oxygenator

Indications for Use *(Describe)*

INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

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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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)*

K180448

Device Name
INSPIRE 8F M Hollow Fiber Oxygenator

Indications for Use *(Describe)*

INSPIRE 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 8F M is intended to be used for 6 hours or less.

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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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)*

K180448

Device Name
INSPIRE 8M Hollow Fiber Oxygenator

Indications for Use *(Describe)*

The INSPIRE 8M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8M is intended to be used for 6 hours or less.

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.

510(κ) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	March 6, 2018
DEVICE TRADE NAME:	INSPIRE 6F M
COMMON NAME:	Hollow fiber oxygenator
CLASSIFICATION NAME, REGULATION & PRODUCT CODE:	Cardiopulmonary Bypass Oxygenator, 870.4350, DTZ Cardiopulmonary Bypass Heat Exchanger, 870.4240, DTR Cardiopulmonary Bypass Arterial Line Blood Filter, 870.4260, DTM
PREDICATE DEVICE:	INSPIRE 6F M (K120185)

DEVICE DESCRIPTION:

The device consists of an oxygenator with an integrated heat exchanger. The INSPIRE model 6F M also has an integrated arterial filter.

The INSPIRE 6F M device can be operated at flow rates up to 6 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli.

The device is a modified version of the currently marketed INSPIRE 6F M products.

INDICATIONS FOR USE:

INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The device modifications are as follows.

1. The size of the gas outlet port was changed from 1/4" to 3/8".
2. The Instructions for Use were revised to reflect the gas outlet port size change and provide additional information regarding moisture and the potential for obstructions.

3. The Instructions for Use were also updated to provide additional information and clarifications about the use of the device.

The modified device has the same fundamental technological characteristics, principles of operation, and control mechanisms as the predicate device.

NON CLINICAL TEST RESULTS:

Additional ISO 10993-1 testing was not required as there were no changes to the device materials.

IN VITRO TEST RESULTS:

Testing was performed to compare devices with the modified and predicate gas outlet port. 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 oxygenating module with the modified gas outlet port successfully met all acceptance criteria for moisture handling.

CONCLUSIONS:

The modified INSPIRE oxygenator has the same intended use, principles of operation and technological characteristics as the predicate. The testing performed demonstrates that the modified INSPIRE oxygenator is substantially equivalent to the predicate.

510(κ) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	March 6, 2018
DEVICE TRADE NAME:	INSPIRE 6M
COMMON NAME:	Hollow fiber oxygenator
CLASSIFICATION NAME, REGULATION & PRODUCT CODE:	Cardiopulmonary Bypass Oxygenator, 870.4350, DTZ Cardiopulmonary Bypass Heat Exchanger, 870.4240, DTR
PREDICATE DEVICE:	INSPIRE 6M (K113626)

DEVICE DESCRIPTION:

The device consists of an oxygenator with an integrated heat exchanger.

The INSPIRE 6M device can be operated at flow rates up to 6 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction 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 is a modified version of the currently marketed INSPIRE 6M products.

INDICATIONS FOR USE:

INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6M is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The device modifications are as follows.

1. The size of the gas outlet port was changed from 1/4" to 3/8".
2. The Instructions for Use were revised to reflect the gas outlet port size change and provide additional information regarding moisture and the potential for obstructions.
3. The Instructions for Use were also updated to provide additional information and clarifications about the use of the device.

The modified device has the same fundamental technological characteristics, principles of operation, and control mechanisms as the predicate device.

NON CLINICAL TEST RESULTS:

Additional ISO 10993-1 testing was not required as there were no changes to the device materials.

IN VITRO TEST RESULTS:

Testing was performed to compare devices with the modified and predicate gas outlet port. 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 oxygenating module with the modified gas outlet port successfully met all acceptance criteria for moisture handling.

CONCLUSIONS:

The modified INSPIRE oxygenator has the same intended use, principles of operation and technological characteristics as the predicate. The testing performed demonstrates that the modified INSPIRE oxygenator is substantially equivalent to the predicate.

510(κ) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	March 6, 2018
DEVICE TRADE NAME:	INSPIRE 8F M
COMMON NAME:	Hollow fiber oxygenator
CLASSIFICATION NAME, REGULATION & PRODUCT CODE:	Cardiopulmonary Bypass Oxygenator, 870.4350, DTZ Cardiopulmonary Bypass Heat Exchanger, 870.4240, DTR Cardiopulmonary Bypass Arterial Line Blood Filter, 870.4260, DTM
PREDICATE DEVICE:	INSPIRE 8F M (K121536)

DEVICE DESCRIPTION:

The device consists of an oxygenator with an integrated heat exchanger. The INSPIRE model 8F M also has an integrated arterial filter.

The INSPIRE 8F M device can be operated at flow rates up to 8 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli.

The device is a modified version of the currently marketed INSPIRE 8F M products.

INDICATIONS FOR USE:

INSPIRE 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 8F M is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The device modifications are as follows.

1. The size of the gas outlet port was changed from 1/4" to 3/8".
2. The Instructions for Use were revised to reflect the gas outlet port size change and provide additional information regarding moisture and the potential for obstructions.

3. The Instructions for Use were also updated to provide additional information and clarifications about the use of the device.

The modified device has the same fundamental technological characteristics, principles of operation, and control mechanisms as the predicate device.

NON CLINICAL TEST RESULTS:

Additional ISO 10993-1 testing was not required as there were no changes to the device materials.

IN VITRO TEST RESULTS:

Testing was performed to compare devices with the modified and predicate gas outlet port. 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 oxygenating module with the modified gas outlet port successfully met all acceptance criteria for moisture handling.

CONCLUSIONS:

The modified INSPIRE oxygenator has the same intended use, principles of operation and technological characteristics as the predicate. The testing performed demonstrates that the modified INSPIRE oxygenator is substantially equivalent to the predicate.

510(κ) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	March 6, 2018
DEVICE TRADE NAME:	INSPIRE 8M
COMMON NAME:	Hollow fiber oxygenator
CLASSIFICATION NAME, REGULATION & PRODUCT CODE:	Cardiopulmonary Bypass Oxygenator, 870.4350, DTZ Cardiopulmonary Bypass Heat Exchanger, 870.4240, DTR
PREDICATE DEVICE:	INSPIRE 8M (K121229)

DEVICE DESCRIPTION:

The device consists of an oxygenator with an integrated heat exchanger.

The INSPIRE 8M device can be operated at flow rates up to 8 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suction 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 is a modified version of the currently marketed INSPIRE 8M products.

INDICATIONS FOR USE:

The INSPIRE 8M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8M is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The device modifications are as follows.

1. The size of the gas outlet port was changed from 1/4" to 3/8".
2. The Instructions for Use were revised to reflect the gas outlet port size change and provide additional information regarding moisture and the potential for obstructions.
3. The Instructions for Use were also updated to provide additional information and clarifications about the use of the device.

The modified device has the same fundamental technological characteristics, principles of operation, and control mechanisms as the predicate device.

NON CLINICAL TEST RESULTS:

Additional ISO 10993-1 testing was not required as there were no changes to the device materials.

IN VITRO TEST RESULTS:

Testing was performed to compare devices with the modified and predicate gas outlet port. 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 oxygenating module with the modified gas outlet port successfully met all acceptance criteria for moisture handling.

CONCLUSIONS:

The modified INSPIRE oxygenator has the same intended use, principles of operation and technological characteristics as the predicate. The testing performed demonstrates that the modified INSPIRE oxygenator is substantially equivalent to the predicate.