June 16, 2017

Sorin Group Italia S.r.l.
c/o Scott Light
Regulatory Affairs Manager
Sorin Group USA, Inc.
14401 W. 65th Way
Arvada, Colorado 80004

Re: K162215
Trade/Device Name: Aortic Arch Cannulae, Optiflow Aortic Arch Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: May 17, 2017
Received: May 18, 2017

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.

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,

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
510(k) Number (if known)  
K162215

Device Name  
Aortic Arch Cannulae  
Optiflow Aortic Arch Cannulae

Indications for Use (Describe)

Aortic Arch Cannulae:  
The device is intended to be used as perfusion cannulae to return arterial blood from the extracorportal circuit to the patient during cardiopulmonary surgery for periods of up to six hours.

Optiflow Aortic Arch Cannulae:  
The device is intended to be used as perfusion cannulae to return arterial blood from the extracorportal circuit to the patient during cardiopulmonary surgery 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

| SUBMITTER:          | Sorin Group Italia  
|                    | 86, Via Statale 12 Nord  
|                    | 41037 Mirandola (MO) Italy |
| CONTACT PERSON:    | Luigi Vecchi  
|                    | Phone: 39 0535 29811  
|                    | Fax: 39 0535 25229 |
| DATE PREPARED:     | May 17, 2017 |
| DEVICE TRADE NAME: | Aortic Arch Cannulae  
|                    | Optiflow Aortic Arch Cannulae |
| COMMON NAME:       | Cardiopulmonary bypass vascular cannulae |
| CLASSIFICATION NAME: | Cardiopulmonary bypass vascular catheter, cannula, or tubing |
| CLASSIFICATION CODE: | DWF |
| REGULATION NUMBER: | 870.4210 |
| PRIMARY PREDICATE DEVICE: | Aortic Arch Cannulae K870825 |
| REFERENCE DEVICE:  | Aortic Arch Cannulae K870826 |

DEVICE DESCRIPTION:
The devices are intended to be used to cannulate the arterial vessels during cardiopulmonary bypass surgery. They are sterile, single use devices.

These cannulae are comprised of three main components:

1. A barbed proximal end connector to attach to cardiopulmonary bypass tubing. A female luer lock connector is also optionally available to provide venting and can be oriented up or down.
2. Single-lumen polymer tubing with an optional wire reinforcement to prevent kinking.
3. A straight or bent tip that is inserted into the patient. The Aortic Arch Cannulae has a mono-dimensional tip design whereas the Optiflow Aortic Arch Cannulae has a three dimensional basket tip design.

INDICATIONS FOR USE:
The device is intended to be used as perfusion cannulae to return arterial blood from the extracorporeal circuit to the patient during cardiopulmonary surgery for periods of up to six hours.
TECHNOLOGICAL CHARACTERISTICS:
The Aortic Arch Cannulae and the Optiflow Aortic Arch Cannulae are modified versions of the cleared Aortic Arch Cannulae (K870825, K870826).

This 510(k) includes the following modifications:

1. The plasticizer used in the cannulae body changed from DEHP to DINCH.
2. The Optiflow Aortic Arch Cannulae use a basket tip design rather than a mono-dimensional tip design.
3. The basket tip design uses polycarbonate rather than ABS as in the mono-dimensional tip design.
4. The Optiflow Aortic Arch Cannulae will be offered with two different sizes of outer diameter, 21Fr and 24Fr rather than 9 to 28 Fr for the A221-xx unmodified device, 9 to 28 Fr for the A222-xx and 9 to 28 Fr for the A232-xx unmodified devices.

The modified devices have the same technological characteristics, principles of operation and control mechanisms as the predicate devices. The modifications do not affect the intended use of the devices.

NON CLINICAL TEST RESULTS:
In order to support the material changes, the applicable tests were conducted in accordance with the requirements of ISO 10993-1 and in conjunction with FDA’s guidance titled “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process”.

IN VITRO TEST RESULTS:
Testing was conducted to demonstrate the modified devices are substantially equivalent to the unmodified devices.

The tests were conducted in accordance with internal methods as well as with the relevant requirements of ISO 10555-1 titled “Intravascular catheters - Sterile and single-use catheters Part 1: General requirements”.

The testing included the following:

1. Blood trauma
2. Peak Tensile Force
3. Structural Integrity
4. Kink resistance
5. Pressure-flow test
6. Shipping/packaging testing

The devices successfully met all acceptance criteria for each of these tests.

CONCLUSION:
The testing performed demonstrates the Aortic Arch Cannulae and Optiflow Aortic Arch Cannulae are substantially equivalent to the predicate Aortic Arch Cannulae (K870825).