DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 8, 2017

Sorin Group Deutschland GmbH
% Scott Light
Regulatory Affairs Manager
Sorin Group USA, Inc.
14401 W 65th Way
Arvada, Colorado 80004

Re: K170460
Trade/Device Name: Sorin CONNECT
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: May 10, 2017
Received: May 11, 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,

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)*

K170460

Device Name
Sorin CONNECT

Indications for Use *(Describe)*

The device is a modularly structured program package that is exclusively used with Sorin/Stockert heart lung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually.

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.

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510(k) SUMMARY

SUBMITTER:	Sorin Group Deutschland GmbH Lindberghstrasse, 25 D-80939 München Germany
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	February 13, 2017
DEVICE TRADE NAME:	Sorin CONNECT
COMMON NAME:	Data Management System
CLASSIFICATION NAME:	Display, cathode-ray tube, medical
UNMODIFIED DEVICE(S):	Sorin CONNECT (K131816)

DEVICE DESCRIPTION:

The Sorin CONNECT is used to collect and view data generated during cardiopulmonary bypass surgery. It interfaces with Sorin Heart-Lung machines to capture this data.

The Sorin CONNECT includes the following main components:

- The Datapad display monitor. It's used to display the collected data.
- The data recording software installed on the Datapad; known as "CONNECT Recorder". It's used to save the collected data.
- The PC software for reviewing data; known as "CONNECT Manager". It's used to view the recorded data and manually enter additional data including clinician's comments.
- An RFID card reader used to transfer the data from the Heartlink card to the Datapad.
- A pole mounting system (holder) to attach the Datapad to an IV pole.

INDICATION FOR USE:

The device is a modularly structured program package that is exclusively for use with Sorin/Stockert heart lung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. Data may be recorded automatically or entered manually.

TECHNOLOGICAL CHARACTERISTICS:

The modified Sorin CONNECT has the same fundamental technological characteristics, principles of operation, and control mechanisms as the unmodified device. The device modifications are described below.

The hardware was updated to replace obsolete components with readily available ones; CPU-board, Solid State Drive (SSD) and WIFI module. A removable CFAST memory was added and

the PS/2 port was removed. The control panel was also changed to a soft-keyboard which includes buttons for brightness control.

The CONNECT Recorder and CONNECT Manager software were upgraded to accommodate the hardware changes, to provide Unique Device Identifier (UDI) information, to avoid the possibility of removing the encryption of patient data in the CONNECT Recorder database, to fix a bug and to provide a notification if a Windows update is available.

K170460

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

NON CLINICAL TEST RESULTS:

The electrical safety of Sorin CONNECT was determined by testing the unit against the IEC 60601-1 electrical safety standard.

The electromagnetic compatibility was also determined by testing the device against the applicable electromagnetic compatibility IEC 60601-1-2 safety standards.

IN VITRO TEST RESULTS:

Verification, validation, and testing activities, were conducted to demonstrate compliance to the product's specifications and compliance to safety and effectiveness requirements.

CONCLUSIONS:

The modified device has the same intended use, principles of operation and technological characteristics as the unmodified device. The testing performed demonstrates substantial equivalence.