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:	December 20, 2013
DEVICE TRADE NAME:	Sorin FlexTherm
COMMON NAME:	Heater-Cooler
CLASSIFICATION NAME:	Controller, temperature, cardiopulmonary bypass
CLASSIFICATION CODE:	DWC
REGULATION NUMBER:	870.4250
UNMODIFIED DEVICE(S):	Stöckert Heater-Cooler System 3T (K052601)

JAN 31 2014

DEVICE DESCRIPTION:

Sorin FlexTherm is designed to provide temperature control during extracorporeal procedures. The device can be used in conjunction with heat exchangers tubing sets and heating/cooling blankets present on the market with an intended use in ECC (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers) and able to withstand a pressure of at least 2 bar. The device is used to warm or cool a patient during cardiopulmonary bypass procedures lasting up to six (6) hours.

As the unmodified device, the Sorin FlexTherm is a software-controlled device provided with hardware elements.
The main components for both devices are the housing provided with wheels, compressor, condenser unit, evaporator, expansion valves, water tanks, heaters, pumps, valves, sensors and a user interface/display.

INDICATION FOR USE:

The Sorin FlexTherm Heater-Cooler System is used with a Stöckert S3 heart-lung machine and / or any other heart-lung machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

The modified device Sorin FlexTherm has the same fundamental scientific technology, operating principles and intended use as the unmodified device.

The changes introduced improve usability and enhance user interface.
The main modifications are the introduction of a newly designed user interface/display, the change of device software and hardware components, change materials of construction (console, hood, tanks, cooling circuit), change of the dimensions, change in power supply.
The Sorin FlexTherm will be offered with a wide range power supply suitable to different voltages (i.e. from 100 – 240 VAC and 50 – 60 Hz).

The labeling and the instructions for use have been updated to reflect the modifications.

There are no significant differences in the packaging scheme.
The basic device function is the same for both the Stöckert Heater-Cooler System 3T and Sorin FlexTherm.

Sorin Group Deutschland GmbH believes that the Sorin FlexTherm is substantially equivalent to the unmodified device and to other currently marketed heater/cooler devices, and raise no new issues of safety and effectiveness.

NON CLINICAL TEST RESULTS:

The electrical safety of Sorin FlexTherm was verified by testing the unit against the IEC 60601-1 electrical safety standard.
The electromagnetic compatibility was also verified by testing the device against the applicable electromagnetic compatibility IEC 60601-1-2 safety standard.

***IN VITRO* TEST RESULTS**:

In vitro testing was performed in order to provide the data necessary to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements.
Comparative tests were performed according to internal methods developed by the manufacturer.
The following table lists the performance tests conducted to demonstrate compliance to the product's performance specifications. The Sorin FlexTherm successfully met all acceptance criteria for each test.

TEST	TEST CLASSIFICATION	TEST TYPE
1	Functional/Performance	Functional performances without patient simulator in terms of system capacity to reach the target temperature, precision of the temperature control and pump capacity.
2	Functional/Performance	Functional performances with patient simulator in terms of cooling/warming a patient and administration of cold/warm cardioplegia.

The SW provided with Sorin FlexTherm was also fully validated.
A functional validation of the software of the entire system was conducted and the software was developed in accordance with Sorin Group Deutschland internal procedures and with consideration of commonly recognized standards of software life cycle processes and quality assurance.
The software documentation was developed according to the requirements of the FDA Guidance for the content of premarket submissions for software contained in medical devices (May 2005) as well as according to the Level of Concern of the device.

CONCLUSIONS:

Based on the information submitted in this 510(k) premarket notification, the Sorin FlexTherm is substantially equivalent to the unmodified device. The Sorin FlexTherm has the same intended use and fundamental scientific technology. The results of *in vitro* studies demonstrate that the Sorin FlexTherm is substantially equivalent to the unmodified device in terms of safety and effectiveness.

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

January 31, 2014

Sorin Group Deutschland GmbH
Scott Light
Sorin Group USA, Inc.
14401 W. 65th Way
Arvada, CO 80004

Re: K140012
Trade/Device Name: Sorin FlexTherm
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: December 31, 2013
Received: January 2, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K140012

Device Name: Sorin FlexTherm

Indications for Use:

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Prescription Use __X___ AND/OR Over-the-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)