K092463

NOV - 5 2009

510(k) Summary
(per 21 CFR 807.92)
Addition of the Sorin B-Care$_5$ to the Stöckert S5 System

1. SPONSOR

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany
Contact Person: Renate Goebert
Telephone: 011 49 89 323 010

Date Prepared: August 10, 2009

2. DEVICE NAME

Proprietary Name:	Stöckert S5 System, Sorin B-Care$_5$
Common/Usual Name:	Heart lung machine, on-line venous blood gas monitor
Classification Name:	Multiple

3. PREDICATE DEVICES

Parent Device: S5 System
Predicate Device (for monitoring of saturation, hematocrit, and temperature): Dideco Data Master (K001388)

4. DEVICE DESCRIPTION

The Stöckert S5 System is a modular system consisting of a console, various pumps, monitors, displays, controls, and user interfaces. This premarket notification adds the B-Care$_5$. The B-Care$_5$ is used for determining oxygen saturation, hematocrit, and temperature in the venous blood circuit.

5. INTENDED USE/INDICATIONS FOR USE

The Sorin B-Care$_5$ is an optional accessory to the Stöckert S5 System and is intended to be used to monitor oxygen saturation, hematocrit, and temperature in the venous blood circuit during cardiopulmonary bypass. The Sorin B-Care$_5$ cannot be used independently and shall only be used with the Stöckert S5 System Console. The Stöckert S5 is indicated

for speed-controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six (6) hours or less, left ventricular venting, cardiotomy suction, and administration of cardioplegia solution, when used by a qualified perfusionist who is experienced in the operation of the S5 System.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified Stöckert S5 System is an upgrade of the parent Stöckert S5 System with the addition of the optional Sorin B-Care$_5$. The modified Stöckert S5 System is substantially equivalent to the parent Stöckert S5 System based on intended use, indication for use, operational characteristics, and fundamental technological characteristics. The performance specifications for the measurements performed by the Stöckert B-Care$_5$ are substantially equivalent to those of the Dideco Data Master.

7. PERFORMANCE TESTING

Testing of the modified Stöckert S5 System (hardware, software, and performance) has demonstrated that the System fulfills prospectively defined performance criteria and that the modified System meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV – 5 2009

Sorin Group Deutschland Gmbh
c/o Medical Device Consultants, Inc.
Ms. Rosina Robinson
49 Plain St.
North Attleboro, MA 02760

Re: K092463
Trade/Device Name: Sorin B-Care$_5$ for the Stockert S5 System
Regulation Number: 21 CFR 870.4220
Regulation Name: Console, Heart-Lung Machine, Cardiopulmonary bypass
Regulatory Class: Class II
Product Code: DTQ
Dated: August 10, 2009
Received: August 11, 2009

Dear Ms Robinson:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Donna R. Lachman

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): K092463

Device Name: Sorin B-Care$_5$ for the Stöckert S5 System

Indications for Use:

The B-Care$_5$ is intended for use as a component part of the Stöckert S5 System during cardiopulmonary bypass for procedures up to six hours. B-Care$_5$ is used exclusively for determining oxygen saturation, hematocrit value, and temperature in the venous blood circuit.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richards

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092463