K091008

JUL 15 2009

510(k) Summary
(Per 21 CFR 807.92)
Stöckert Centrifugal Pump System

1. SPONSOR

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

Date Prepared: July 7, 2009

2. DEVICE NAME

Proprietary Name:	Stöckert Centrifugal Pump Plus System (SCP Plus)
Common/Usual Name:	Centrifugal pump system
Classification Name:	Cardiopulmonary bypass speed control device

3. PREDICATE DEVICES

Stöckert Centrifugal Pump System

4. DEVICE DESCRIPTION

The modified Stöckert Centrifugal Pump System (referred to as the SCP Plus) is an optional accessory to the S3 or S5 System, a modular system consisting of a console, various pumps, monitors, displays, controls, and user interfaces.

5. INTENDED USE/INDICATIONS FOR USE

The Stöckert Centrifugal Pump Plus System (SCP Plus) is a cardiopulmonary bypass speed control device (*21 CFR 870.4380*) that is indicated for use with the COBE Revolution Pump Head/Dideco Synergy/ECC.O for speed-controlled pumping through a cardiopulmonary bypass circuit for typical durations of six hours or less. The SCP Plus is intended to be used with the S3 or S5 System and the Stöckert Air Purge Control (APC) System.

The SCP Plus has been qualified only for typical durations of six hours or less, appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies for long-term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified Stöckert Centrifugal Pump System (referred to as the SCP Plus) is an upgrade of the parent SCP System. The modified SCP System is substantially equivalent to the parent SCP System based on intended use, indication for use, operational characteristics, and fundamental technological characteristics.

7. PERFORMANCE TESTING

Testing of the Stöckert Centrifugal Pump Plus System has demonstrated that the System continues to fulfill prospectively defined performance criteria and that the modified System meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

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

Re: K091008
Stockert Centrifugal Pump Plus System (SCP Plus), models 60-00-10, 60-00-55
Regulation Number: 21 CFR 870.4380
Regulation Name: Control, pump speed, cardiopulmonary bypass
Regulatory Class: Class II (two)
Product Code: DWA
Dated: July 7, 2009
Received: July 8, 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K091008

Device Name: Stöckert Centrifugal Pump Plus System

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

Number K091008