JUN - 6 2006

K052601

Traditional 510(k) Premarket Notification
510(k) Summary
Sorin Group Deutschland GmbH, Stöckert Heater-Cooler System 3T

1. SUBMITTER/HOLDER

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010

Date Prepared: September 19, 2005

2. DEVICE NAME

Proprietary Name: Stöckert Heater-Cooler System 3T
Common/Usual Name: Heater-Cooler
Classification Name: Cardiopulmonary bypass temperature controller

3. PREDICATE DEVICE

- Cincinnati Subzero Hemotherm (CSZ Hemotherm) (K811742)
- Alpha Omega, Inc. Dual^2 Cooler-Heater (K001520)
- Jostra AB Heater-Cooler Unit 30 (K031544)

4. DEVICE DESCRIPTION

The Sorin Group Deutschland GmbH Stöckert Heater-Cooler System 3T consists of standard and optional components. The standard components comprise the heater-cooler base unit, water connectors, CAN-connecting cable for the S3 System, potential equalization cable, and Operating Instructions. Patient blankets used with the System are already legally marketed in the United States.

5. INTENDED USE

The Stöckert Heater-Cooler System 3T is intended to provide temperature-controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Heater-Cooler System 3T to the cited predicate devices based on equivalence in intended use, fundamental technological and operational characteristics. Testing submitted in this premarket notification demonstrates that the Stöckert Heater-Cooler System 3T complies with specifications, meets user requirements, and the differences between the proposed device and cited predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, MA 02760

Re: K052601
Stockert Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary Bypass Temperature Controller
Regulatory Class: Class II
Product Code: DWC
Dated: May 15, 2006
Received: May 16, 2006

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

Indications for Use

510(k) Number: K052601

Device Name: Stöckert Heater-Cooler System 3T

Indications for Use:

The Stöckert Heater-Cooler System 3T 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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of **Cardiovascular Devices**

510(k) Number K052601