K062396

SEP 2 8 2006

APPENDIX C

510(k) Summary

510(k) Summary
Sorin Group Deutschland GmbH
Stöckert S5 System
(per 21 CFR 807.92)

1. SPONSOR

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

Date Prepared: August 15, 2006

2. DEVICE NAME

Proprietary Name: Stöckert S5 System
Common/Usual Name: Heart lung machine
Classification Name: Multiple

3. PREDICATE DEVICES

Stöckert S5 System

4. DEVICE DESCRIPTION

The modified Stöckert S5 System, like the parent S5 System, is a modular system consisting of a console, various pumps, monitors, displays, controls, and user interfaces.

5. INTENDED USE

The Stöckert S5 System is intended to be used during cardiopulmonary bypass surgery lasting six (6) hours or less.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified Stöckert S5 System is an upgrade of the parent Stöckert S5 System. 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.

7. PERFORMANCE TESTING

Testing of the modified Stöckert S5 System (hardware and software) 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
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2006

Medical Device Consultants, Inc.
c/o Ms. Rosina Robinson
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, MA 02760

Re: K062396
Stöckert S5 System
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart Lung Machine Console
Regulatory Class: Class II (two)
Product Code: DTQ
Dated: September 18, 2006
Received: September 19, 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 (301) 443-6597 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): K062396

Device Name: Stöckert S5 System

Indications for Use:

The Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

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)

Donna R. Vochmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062396