SEP 2 3 2004

K042374

# Special 510(k): Device Modification
# 510(k) Summary for
# Stöckert SCP Rhythm

## 1. SPONSOR

Stöckert Instrumente GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
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Date Prepared: August 31, 2004

## 2. DEVICE NAME

Proprietary Name: Stöckert SCP Rhythm

Common/Usual Name: Cyclic RPM Control

Classification Name: Accessory to cardiopulmonary bypass console

## 3. PREDICATE DEVICE

Stöckert S3 Cyclic RPM Control Module (K971520)

## 4. DEVICE DESCRIPTION

The Stöckert SCP Rhythm is a modification of the S3 Cyclic RPM Control Module. The modifications consist of two changes: (1) a change to the artwork of the display panel to show SCP Rhythm rather than Cyclic RPM Control and (2) firmware and software modifications. No modifications are being made to the hardware or electronics of any of the components. The Stöckert SCP Rhythm is intended for use with the SCP System as mounted on an S3 Cardiopulmonary Bypass Console.

## 5. INTENDED USE

The Stöckert SCP Rhythm is an accessory to the S3 Cardiopulmonary Bypass Console that allows for cyclically controlled delivery of blood with the Stöckert SCP during cardiopulmonary bypass for periods of up to six hours.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Stöckert SCP Rhythm is identical in intended use and fundamental scientific technology to the parent Stöckert S3 Cyclic RPM Control. The differences between the proposed and parent device are limited to the display panel and firmware/software. Stöckert Instrumente GmbH has verified and validated the device modifications and has demonstrated, through the testing provided in the 510(k), that the Stöckert SCP Rhythm complies with specifications, meets user requirements, and the differences between the parent and the proposed device 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

SEP 23 2004

Medical Device Consultants, Inc.
c/o Ms. Rosina Robinson
Senior Staff Consultant
49 Plain Street
North Attleborn, MA 02760

Re: K042374
Stöckett SCP Rhythm
Regulation Number: 21 CFR 870.9380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II (two)
Product Code: DWA
Dated: August 31, 2004
Received: September 1, 2004

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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

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): K042374

Device Name: Stöckert SCP Rhythm

Indications for Use:

The Stöckert SCP Rhythm is an accessory to the S3 Cardiopulmonary Bypass Console that allows for cyclically controlled delivery of blood with the Stöckert SCP during cardiopulmonary bypass for periods of up to six hours.

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)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042374