JUL 0 2 2004

K041558

Special 510(k): Device Modification
510(k) Summary for
Stöckert Air Purge Control

1. SPONSOR

Stöckert Instrumente GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010
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Date Prepared: June 30, 2004

2. DEVICE NAME

Proprietary Name: Stöckert Air Purge Control (APC) System
Common/Usual Name: Cardiopulmonary bypass bubble detector and sensor
Classification Name: Cardiopulmonary bypass bubble detector

3. PREDICATE DEVICE

Stöckert S3 Level Control and Bubble Detector (K955152)

4. DEVICE DESCRIPTION

The Stöckert Air Purge Control is a modification of the cleared S3 Level Control/Bubble Detector with the new Air Purge Control module replacing the Bubble Detector. The APC System uses the same Level Control module, Level Control sensor as the predicate device above. The modifications being made to the parent Stöckert S3 Level Control and Bubble Detector consist of three changes: (1) a change to the artwork of the display panel to show "APC" rather than "Bubble Detector," (2) replacement of the "Alarm Clear" key with the "Purge Control" key,

and (3) firmware and software modifications. No modifications are being made to the hardware or electronics of any of the components.

5. INTENDED USE

The Stockert Air Purge Control (APC) detects air in the venous line and removes air from the venous bubble trap of the Synergy System tubing circuit that is intended to be used with the Stockert S3 Perfusion System. The S3 System is indicated for speed-controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six 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 S3 System.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed APC is identical in intended use and fundamental scientific technology to the parent Stöckert S3 Level Control and Bubble Detector. The differences between the proposed and parent device is 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 APC System 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

JUL 0 2 2004

Stöckert Instrumente GmbH
c/o Ms. Rosina Robinson
Senior Staff Consultant
Medical Devices Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K041558
Stöckert Air Purge Control
Dated: June 9, 2004
Received: June 10, 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,

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): K041558

Device Name: Stöckert Air Purge Control

Indications for Use:

The Stockert Air Purge Control (APC) detects air in the venous line and removes air from the venous bubble trap of the Synergy System tubing circuit that is intended to be used with the Stockert S3 Perfusion System. The S3 System is indicated for speed-controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six 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 S3 System.

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)

Diana R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041558