K032213

AUG 2 9 2003

Special 510(k): Device Modification
510(k) Summary for
Stöckert Centrifugal Pump System with Tubing Clamp

1. SPONSOR

Stöckert Instrumente GmbH
Lindberghstrasse 25
80939 Munich
Germany

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Date Prepared: July 18, 2003

2. Device Name

Proprietary Name: Stöckert Centrifugal Pump System with Tubing Clamp
Common/Usual Name: Centrifugal pump
Classification Name: Cardiopulmonary bypass speed control device

3. Predicate Devices

- Stöckert Centrifugal Pump (K011838)
- Automatic Tubing Clamp Safety System (ATC) (K961364)

4. Device Description

The Stöckert Centrifugal Pump System with Tubing Clamp (SCP System TC) is a modification of the Stöckert Centrifugal Pump (SCP). The proposed SCP System TC is identical in intended use and fundamental scientific technology to the parent SCP. The parent SCP is identical to the proposed SCP System TC with the exception of the addition of an Electrical Remote-Controlled Tubing Clamp (Tubing Clamp) that is positioned at the pump outlet to occlude the arterial line. The Tubing Clamp is designed to automatically close if the reservoir blood level, microbubble activity, flow rate, or retrograde flow in the extracorporeal circuit reaches alarm levels during a cardiopulmonary bypass procedure. The Tubing Clamp can also be manually

opened and closed by the operator via membrane keys on the SCP Pump Control Panel.

5. INTENDED USE

Both the proposed SCP System TC and the parent SCP System are cardiopulmonary bypass speed control devices indicated for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less. Neither the proposed or parent SCP has 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.

The SCP System TC controls a Tubing Clamp that is positioned at the pump outlet to occlude the arterial line if the reservoir blood level, microbubble activity, or retrograde flow in the extracorporeal circuit reaches alarm levels during a cardiopulmonary bypass procedure.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

As stated earlier, the proposed SCP System TC is identical in intended use and fundamental scientific technology to the parent SCP System. The modifications made to the parent SCP System to produce the proposed SCP System TC are limited to the addition of the Tubing Clamp that is positioned at the pump outlet to occlude the arterial line.

The proposed Tubing Clamp is connected to the Stöckert Centrifugal Pump Console (SCPC System) or a Stöckert Compact (SC) or Stöckert S3 System (S3) heart-lung machine console via a CAN/24V connection cable. Mains power and emergency power is provided by the connected SCPC System or SC/S3 System. Both automatic and manual operation of the clamp is controlled via the SCP System microprocessor control system.

The ATC tubing clamps automatically close on the cardiopulmonary bypass circuit tubing when alarm limits for microbubble activity or retrograde flow reaches set levels. There is also a mechanism for manual override. However, the predicate ATC is a stand-alone device containing a power source, air and flow detection units, user interface, and control elements in addition to the tubing clamps.

The addition of the Tubing Clamp to the SCP represents a minor design change that raises no new issues of safety or effectiveness. Therefore Stöckert Instrumente GmbH believes that the SCP System TC is substantially equivalent to the SCP.

7. PERFORMANCE TESTING

Electrical safety and electromagnetic compatibility testing was performed to demonstrate conformance with the appropriate standards. Functional acceptance testing, hardware and software testing, and validation testing was performed to confirm that the Tubing Clamp performs as designed and met user requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Mr. Helmut Hofl
Director, Quality Assurance & Regulatory Affairs
Stockert Instrumente GmbH
Lindberghstrasse
D-80939 Muenchen
Germany

Re: K032213
Stockert Centrifugal Pump System with Tubing Clamp
Regulation Number: 21 CFR 870.4360
Regulation Name: Control, Pump Speed, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWA
Dated: July 18, 2003
Received: July 21, 2003

Dear Mr. Hofl:

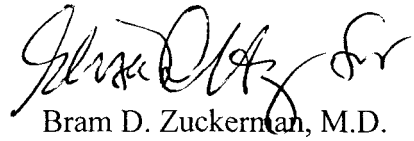
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. 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/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

510(k) Number (if known): K032213

Device Name: Stöckert Centrifugal Pump System with Tubing Clamp

Indications for Use:

The Stöckert Centrifugal Pump System with Tubing Clamp (SCP System TC) is a cardiopulmonary bypass speed control device that is indicated for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less. The SCP System TC 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.

The SCP System TC controls a Tubing Clamp that is positioned at the pump outlet to occlude the arterial line if the reservoir blood level, microbubble activity, or retrograde flow in the extracorporeal circuit reaches alarm levels during a cardiopulmonary bypass procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032213

Prescription Use X
(Per 21 CFR 801.109)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)