K972321

510(k) SUMMARY
STÖCKERT S3 PERFUSION SYSTEM MAST PUMP MODULE

FEB 27 1998

1. ***Date Prepared:*** June 20, 1997

2. ***Submitter:*** Stöckert Instrumente, GmbH
Lilienthalallee 5-7
D-80939 Munich, Germany

3. ***Contact:*** Helmut Höfl
011-49-89-32301-0

4. ***Device Name:*** Stöckert S3 Perfusion System
Mast Pump Module

5. ***Device Classification:*** Cardiopulmonary bypass roller-type pumps have been classified as Class II devices in 21 CFR 870.4370 (Product Code: 74 DWB).

6. ***Device Description and Comparison to Predicate Products:***

The Stöckert S3 (cardiopulmonary bypass) Mast Pump Module is intended for use during cardiopulmonary bypass surgery. The S3 Mast Pump Module is a component of the Stöckert S3 Perfusion System, and is intended to provide speed controlled pumping of fluid through the cardiopulmonary bypass circuit, left ventricular venting, cardiotomy suction, or the administration of cardioplegia solution. The predicate and predecessor device to the S3 Mast Pump Module is the S3 Double Head Pump Module. The S3 Mast Pump has the same double head pump design and intended use as the S3 Double Head Pump Module(K955038). The basic difference between these two double head pumps is that for the Mast Pump, the pump heads are mounted on the mast of an S3 Mast Pump Extension Unit, and the control/operating unit is placed on a swivel plate on the console, whereas for the standard S3 double head pump module, the control unit is mounted directly over the pump heads and the entire module is installed on the S3 Console Base. The Mast Pump configuration

enables the perfusionist to position the pump heads in close proximity to the patient, thus reducing the length of tubing required for the extracorporeal blood circuit and the associated priming volume required. This option is useful in clinical situations where it is important to minimize the amount of tubing in the circuit, e.g. infant perfusion.

Information supplied in this premarket notification to support a determination of substantial equivalence for this device included descriptive information about the design, materials, and intended use of the device, as well as extensive testing results characterizing device performance and software verification and validation.

The Stöckert S3 Perfusion System console and modular components (including the Mast Pump Module) conform with the applicable requirements of IEC 601, IEC 62a, and UL 544.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

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

Re: K972321
Stöckert S3 Mast Pump
Regulatory Class: II (Two)
Product Code: 74 DWB
Dated: January 22, 1998
Received: January 23, 1998

Dear Ms. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972321

Device Name: **Stöckert S3 Mast Pump Module**

Indications For Use:

The Stöckert S3 Mast Pump is a modular component of the Stöckert S3 Perfusion System. The S3 Mast Pump is intended to provide speed controlled pumping of blood through the cardiopulmonary bypass circuit for durations of normally six hours or less, left ventricular venting, cardiotomy suction, or the administration of cardioplegia solution, when used by a qualified perfusionsist who is experienced in the operation of the S3 System.

(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, Respiratory,
and Neurological Devices
510(k) Number K972321

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____