

K982014

SEP 4 1998

510(k) Summary
Special 510(k): Device Modification
Stöckert Compact System
(per 21 CFR 807.92)

1. SPONSOR/APPLICANT

Stöckert Instrumente GmbH
 Lilienthalallee 5-7
 D-80939 Munich 45, Germany

Contact: Helmut Höfl,
 Manager, Quality Assurance

Telephone: 011 49 89 323 010

Facsimile: 011 49 89 323 4238

2. DEVICE NAME

Proprietary Name: Stöckert Compact System (SC System)

Common/Usual Name: Heart Lung Machine

Classification Names: Multiple (See Table E-1)

Table E-1. SC System Classifications

Classification Name	21 CFR	ProCode
Cardiopulmonary bypass heart-lung console	870.4220	74DTQ
Roller type cardiopulmonary bypass blood pump	870.4370	74DWB
Cardiopulmonary bypass pump speed control	870.4380	74DWA
Cardiopulmonary bypass bubble detector	870.4205	74KRL
Cardiopulmonary bypass level sensing monitor/control	870.4340	74DTW
Accessory to the cardiopulmonary bypass console: Temperature Monitor	870.4220	74DTQ
Accessory to the cardiopulmonary bypass console: Timer	870.4220	74DTQ
Cardiopulmonary bypass coronary pressure gauge	870.4310	74DXS
Optional SC System Accessories		
Venous Line Clamp (<i>Class I and Exempt</i>)	870.4200	74KRI

3. PREDICATE DEVICES

Stöckert S3 System Modules: Multiple 510(k) Numbers

4. INTENDED USE

The Stöckert Compact System is an integrated heart-lung machine consisting of pumps, monitoring, and control elements on a single chassis. It is indicated for speed controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less, left ventricular venting, cardiotomy suction, administration of cardioplegia solution, when used by a qualified perfusionist who is experienced in the operation of the SC System.

The SC System has been qualified only for durations appropriate to cardiopulmonary bypass procedures and 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.

5. DEVICE DESCRIPTION

The Stöckert Compact System is a modification of the Stöckert S3 System, which integrates its components into a single chassis. There is no change to the indications for use or the fundamental technological characteristics.

6. BASIS FOR DETERMINATION OF EQUIVALENCE

The Stöckert Compact System is a modification of the Stöckert S3 System and is therefore substantially equivalent to the S3 System. This determination is based on equivalence in intended use and technological characteristics (design and operation). System modifications have been validated according to Stöckert Instrumente Design Control procedures, in compliance with the Quality Systems Regulations. Stöckert Instrumente GmbH also believes that any differences between the SC and S3 Systems are minor and raise no new issues of System safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982014
Stöckert Compact System
Regulatory Class: II
Product Code: DTQ
Dated: August 4, 1998
Received: August 5, 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 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). 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 (Pre-market 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 pre-market 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.

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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/dsma/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

510(k) Number (if known): K982014

Device Name: Stöckert Compact System

Indications For Use:

The SC System is an integrated heart lung machine consisting of pumps and monitoring and control elements on a single chassis. It is indicated for speed controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less, left ventricular venting, cardiotomy suction, administration of cardioplegia solution, when used by a qualified perfusionist who is experienced in the operation of the SC System.

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(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 K982014

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use