

K77720

SEP 10 1997

## Appendix F

### 510(k) Summary

## 510(k) SUMMARY

### STÖCKERT S3 PERFUSION SYSTEM CYCLIC RPM CONTROL MODULE

1. **Date Prepared:** April 24, 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  
Cyclic RPM Control Module
  
5. **Device Classification:** Class II, 21 CFR 870.4370
  
6. **Device Description and Comparison to Predicate Products:**

The Stöckert S3 Cyclic RPM Control Module is an accessory module to the Stöckert S3 (cardiopulmonary bypass) Perfusion System, and is intended to allow the roller pump or double head pump to operate in the pulsed flow mode. The predicate and predecessor device to the S3 Cyclic RPM Control Module is the Stöckert-Shiley CAPS PFC 100 S Control unit (K883456). Similar devices have been used for many years for this same intended purpose. The new S3 Cyclic RPM Control Module is a simple upgrade of the technological aspects of the predicate device, e.g., the software controls and have been updated and the control and display panels have been updated for user convenience in operating the system.

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. Testing included electrical testing, functional acceptance testing, and software verification and validation testing. The Stöckert S3 Perfusion System, including the Cyclic RPM Control Module, conforms with the applicable requirements of IEC 601, and IEC 62a. The manufacturing facility is ISO 9001 certified, and the device holds the CE mark in the European Union.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

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

SEP 10 1997

Re: K971520  
Stöckert S3 Cyclic RPM Control Module  
Regulatory Class: II (Two)  
Product Code: 74 DWB  
Dated: August 6, 1997  
Received: August 8, 1997

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 (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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

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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/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

870. 43 0 - DWB II Roller-type CPB Blood Pump  
876. 42 00 - CPB Accessory Equipment

510(k) Number (if known): K 97 1520

Device Name: Stöckert S3 Bypass System Cyclic RPM Control Module

Indications For Use:

The Stöckert S3 Cyclic RPM Control Module is an accessory to the S3 Cardiopulmonary Bypass System Console which allows for the cyclic rpm control of an S3 pump.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 97 1520

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)