K992635

DEC 20 1999

Special 510(k) Summary
Stöckert Instrumente
Interface Module IDDD

1. Sponsor/Applicant Name, Address, Telephone Number

Stöckert Instrumente GmbH
Lilienthalalee 5-7
D-80939 Munich
Germany

Contact Person: Helmut Höfl

Date of Summary Preparation: August 5, 1999

2. Device Name

Proprietary Name: Interface Module IDDD
Common/Usual Name: Interface Module
Classification Name: Accessory to Cardiopulmonary bypass heart lung machine

3. Identification of the Predicate or Legally Marketed Device(s) to Which Equivalence Is Being Claimed

Stöckert S3 Heart Lung Machine (K950990)
Stöckert SC Heart Lung System (K982014)
Stöckert-Shiley HLM Interface Module (K983541)

4. Device Description

The Stöckert Interface Module IDDD is an addition to the Stöckert S3 heart lung machine (K950990) and the SC heart lung system (K982014), which were both previously cleared for marketing. The Interface Module IDDD provides serial data output from the Stöckert S3 and SC Heart Lung Machines for recording data on an external PC or other recording devices. Serial output information from external devices like blood gas analyzers or patient monitors can also be input to the Interface Module IDDD to be passed through to the serial output. The Interface

Module IDDD is installed into the Electronics and Power Supply Pack (E/P) of the S3 or the Sensor Module Rack of the SC. A CAN bus system manages the data transfer.

5. INTENDED USE

The Stöckert S3 heart lung machine and the SC heart lung system are integrated heart lung machines for cardiopulmonary bypass. The Interface Module IDDD provides serial data output from the Stöckert S3 and SC Heart Lung Machines for recording data on an external PC or other recording devices. Serial output information from external devices like blood gas analyzers or patient monitors can also be input to the Interface Module IDDD to be passed through to the serial output. The output protocol provides a complete overview on all relevant data obtained from the heart lung machine as well as from external devices. The serial output data are intended for procedure documentation and are not intended for making clinical decisions for diagnosis.

6. A STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) CITED

The S3 and SC Interface Module IDDD is substantially equivalent to the HLM Interface Module of the Stöckert-Shiley CAPS System, in that they are both intended to link a heart lung machine to user-selected, peripheral instruments, allowing data to be displayed on the DMS software or recorded and displayed on a user-selected PC (not provided).

The STÖCKERT Interface Module IDDD and the HLM Interface Module of the Stöckert-Shiley CAPS System both feature a module that gathers and processes data delivered not only from the heart lung machine module but also from other instruments such as patient monitors or blood gas analyzers. Using the DMS Software or in the case of the CAPS machine, specially designed perfusion software, the perfusionist can record the course of perfusion.

7. TESTING:

All electrical testing, including electrical safety and electromagnetic compatibility was conducted on the Stöckert S3 System with an Interface Module IDDD installed.

Testing for electrical safety and functional safety (according to IEC 60601-1) was performed using both SC and S3 Systems with an Interface Module IDDD installed. Testing for electromagnetic compatibility (emissions and immunity) was conducted on the STÖCKERT S3 Perfusion System with all S3 System components and accessories in place on the console including the Interface Module IDDD, during operation in no-load and full-load states.

During EMI/EMC testing, all pump heads were running at 100 RPM. The S3 System was connected to the AC line. The Interface Module IDDD passed the EMI/EMC testing. The pass criteria consisted of no pump stops, no pump runaway, no sensor alarms, stable displayed values and a correctly functioning IDDD after testing.

Testing was performed to determine if the functions of the SC and S3 heart-lung systems are affected by the addition of the Interface Module IDDD. The testing was performed, in part, to show that the safety critical pump functions worked correctly with the IDDD Module in place. The second part of the test consisted of a code inspection of all CAN receivers to determine that the filters only accept the CAN messages specified for the respective module. The code inspection showed that CAN messages from the IDDD are only accepted by the CDM (set messages) and by IDDD modules themselves (data messages). IDDD messages are not accepted by other CAN receivers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

Stockert Instrumente
c/o MDCI
49 Plain Street
North Attleboro, MA 02760
Attn: Mary McNamara-Cullinane

Re: K992635
Interface Module IDDD
Regulatory Class: II (two)
Product Code: KRI, DTQ
Dated: December 3, 1999
Received: December 6, 1999

Dear Ms. McNamara-Cullinane:

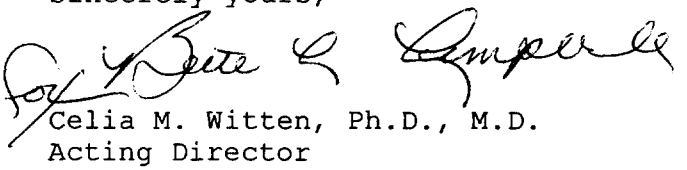
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (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" (21CFR 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992635

Device Name: Stöckert Instrument Interface Module IDDD

Indications for Use:

The Stöckert S3 heart lung machine and the SC heart lung system are integrated heart lung machines for cardiopulmonary bypass. The Interface Module IDDD provides serial data output from the Stöckert S3 and SC Heart Lung Machines for recording on an external PC or other recording devices. Serial output information from external devices like blood gas analyzers or patient monitors can also be input to the Interface Module IDDD to be passed through to the serial output. The output protocol provides a complete overview of all relevant data obtained from the heart lung machine as well as from external devices. The serial output data are intended for procedure documentation, and are not intended for making clinical decisions for diagnosis.

(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 K992635

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