510(k) Summary
(per 21 CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)*
Stöckert Gas Blenders

1. SPONSOR

Sorin Group Deutschland GmbH
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Germany
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DEC - 9 2010

Date Prepared: December 2, 2010

2. DEVICE NAME

Proprietary Names:	Stöckert Gas Blender
Common/Usual Names:	Gas blender for heart lung machines
Classification Names:	Gas control unit, cardiopulmonary bypass (21 CFR 870.4300; Product Code: DTX)

3. PREDICATE DEVICES

Sechrist Model 3500CP-G Air/Oxygen Mixer (K023745; Product Code: DTX; 21 CFR 870.4300)

4. DEVICE DESCRIPTION

Physical Description

The Stöckert Gas Blender Base Unit is 200 mm wide, 185 mm high, and 270 mm deep and it weighs 2.5 kg. It can be used either from a suitable horizontal surface such as a table or cart or it can be mounted on one of the masts (using the mast holder). It is attached to HLM console with the supplied 24V/CAN connector. This connection provides both power and communication between the Stöckert Gas Blender and the System Display Panel of the HLM. The Stöckert Gas Blenders are designed to provide a maximum mixed gas flow rate of 2L/min, 5L/min or 10 L/min depending on the model used to allow the perfusionist to purge the oxygenator with gas during the priming process.

The front panel is the user interface and includes the on/off key, displays and controls. The rear panel houses the three inlet gas connections, the gas mix outlet, and the 24V/CAN connector. Gas line connectors are fast release connectors, consisting of a male connector (installed on the tubing) and a coupler socket (on the housing of the Gas Blender). Both sets (male and female) of connectors are labeled with the respective gas for which they are intended to be used.

How the Device Functions

The Stöckert Gas Blenders enable the qualified perfusionists who are managing the cardiopulmonary bypass circuit using a Stöckert S5 or Sorin C5 System to precisely set, monitor and control the gas flows required for the oxygenation of the patient's blood during extracorporeal circulation. The supply sources for air, O_2 and CO_2 are connected to the rear inlets of the Stöckert Gas Blender and the gas mixture outlet is connected to the oxygenator (*not supplied*).

Scientific Concepts That Form the Basis for the Device

Cardiopulmonary bypass procedures require oxygenation of the patient's blood while the heart and lungs are at rest.

Significant Physical and Performance Characteristics of the Device, such as Device Design, Material Used, and Physical Properties

The Stöckert Gas Blenders are optional accessories to and designed to be operated with the Stöckert S5 System/Sorin C5 System. They cannot be operated independently from the heart lung machine console. The values for total gas flow (air + O_2), FiO_2 and CO_2 can be adjusted independently without affecting the remaining two values. Gas flow is displayed at both the Stöckert Gas Blender base unit and the remote display module situated in the Stöckert S5 System/Sorin C5 System "control desk" or "System Panel." Set values and actual values are continuously monitored and any discrepancy between them causes both optical and acoustic alarms. If desired, the perfusionist may set alarm limits at the remote display module to monitor the blood flow/gas flow ratio for the arterial pump.

5. INTENDED USE/INDICATION FOR USE

The Stöckert Gas Blenders (2L, 5L, and 10L) are intended to enable qualified personnel to set monitor and control gas flows of medical grade gases (air/O_2/CO_2) during cardiopulmonary bypass. The Stöckert Gas Blenders are used as components of or optional accessories to the Stöckert S5 System (or any compatible Sorin system using the S5 firmware versions of 3.0 or greater) for periods of six hours or less.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Gas Blender to the cited predicate devices based on equivalence in intended use, physical design, fundamental technological, and operational characteristics. Information and testing submitted demonstrates that there are no new issues of safety and effectiveness.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Design verification and validation testing presented in the 510(k) included electrical/safety testing (IEC60601-1), EMI/EMC testing (IEC60601-1-2), and Functional Acceptance testing, and design validation testing (internal and external).

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No formal clinical testing was provided as the basis for substantial equivalence or is required.

9. SUMMARY OF OTHER INFORMATION

Non-US marketing history for the Stöckert Gas Blender was submitted.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Testing and information demonstrates that the Stöckert Gas Blender meet prospectively defined design and performance specifications and that they are substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

DEC - 9 2010

Re: K101046
Trade/Device Name: Stöckert Gas Blenders
Regulation Number: 21 CFR 870.4300
Regulation Name: Cardiopulmonary bypass gas control unit
Regulatory Class: II
Product Code: DTX
Dated: October 26, 2010
Received: October 27, 2010

Dear Ms. Robinson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101046

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Device Name: Stöckert Gas Blenders

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuhner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101046