April 5, 2021

LivaNova Deutschland GmbH
Florian Goetz
Specialist Regulatory Affairs
Lindberghstr. 25
Munich, Bavaria 80939
Germany

Re: K210130
Trade/Device Name: S5 System
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: March 18, 2021
Received: March 22, 2021

Dear Florian Goetz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

for Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210130

Device Name
Stöckert S5 System

Indications for Use *(Describe)*
The Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Stöckert S5 System

APPLICANT

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Primary contact person	**Alternate contact person**
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Date Prepared: March 18, 2021

APPLICATION CORRESPONDENT

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DEVICE INFORMATION

Proprietary Name:	Stöckert S5 System
Common/Usual Name:	Heart-Lung Machine
Classification Name:	Console, Heart-Lung Machine, Cardiopulmonary Bypass Console
Classification Panel:	74 Cardiovascular
Device Class:	Class II
Regulation Number:	21 CFR §870.4220
Product Code:	DTQ

PREDICATE DEVICE INFORMATION

The modified Stöckert S5 System is substantially equivalent in function and intended use to the Stöckert S5 System cleared in Premarket Notification K071318.

INDICATIONS FOR USE

The Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

COMPARISON OF THE INDICATIONS FOR USE

It is noted that the 510(k) Summary of K071318 (the predicate S5 System) provides Indications for Use that are specific to the Pulse Mode Control module that was introduced with K071318 in addition to the Indications for Use for the entire S5 System.

The predicate S5 System as last cleared with K071318 on 07/06/2007 was found to be substantially equivalent to the previously cleared S5 System (K062396 on 09/28/2006) and the originally cleared S5 System (K060053 on 06/02/2006). The Indications for Use for the S5 System did not substantially change due to the additional wording specific to Pulse Mode Control.

Therefore, the modified S5 System's Indications for Use are the same as the predicate S5 System, with the exception that the Pulse Mode Control specific wording is not included, thus returning the Indication for Use to its original verbiage.

DEVICE DESCRIPTION

The S5 System is configurable to user needs with different system components. The main configurable and optional system components consist of:

Console

The Console provides a mobile chassis containing the power supply and several functional units that allow the speed-controlled pumping of blood and accessories for monitoring and safety.

System Panel

The S5 system panel contains the display and control modules for all of the monitoring, control and measuring devices and is, alongside the pump control panel, another interface between the operator and the S5 System.

Pumps

Pumps may be console or mast mounted and either roller or centrifugal pump type. Pumps provide speed-controlled pumping of flow in the ECC (Extra Corporeal Circulation) using a peristaltic (positive displacement) pump or using a roto-dynamic pump (non-occlusive), automatic clamping and pump control according to measured flow rate and direction

Bubble detector

Monitoring device that detects air bubbles and microbubbles in the ECC – if detected, a visual and acoustic alarm is triggered, and the pump stops.

Level control

The level monitor controls the blood level in the oxygenator/reservoir.

Display, alarm generation and pump speed regulation based on detection of blood level in a venous reservoir within the ECC.

Temperature monitor

The temperature monitor allows the simultaneous measurement and display of up to four temperatures, as measured by connected temperature probes.
Display and alarm generation based on measurement of temperature of flow within the ECC.

Pressure control

The pressure sensor module is used to measure and display the pressure in the extracorporeal circuit.
Display, alarm generation and pump speed regulation based on measurement of pressure in the ECC.

Cardioplegia Control

The Cardioplegia control unit can be used with the roller pumps RP 150 or a DRP 85 to deliver cardioplegic solutions or blood cardioplegia during an operation to the patient.

Electronic gas blender

May be connected to allow the operator to set, monitor, and display the gas flows required for ECC.

Serial Data interface

Transfer of data from non-proprietary external devices to a proprietary data management system.

Venous line clamps (manual)

Provides a separate control unit and line clamp.

Electrical venous occlude (EVO)

The clamp closes automatically when the stop link function to the arterial pump is activated.

A schematic of S5 System is provided on the following page.

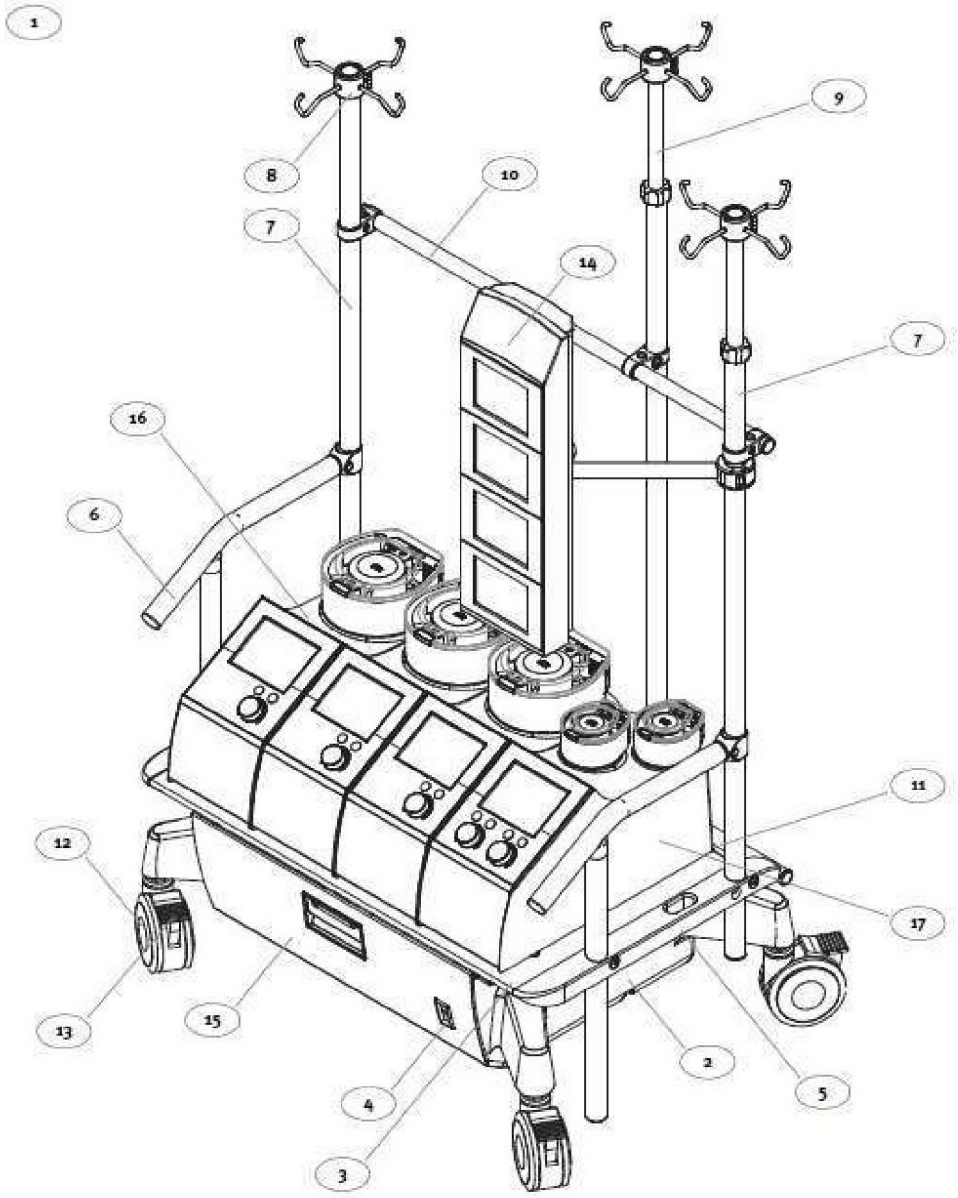

Figure 1: Schematic of S5 System

Table 1: Components of S5 System Schematic

Item	Name	Function
1	S5 System	Perform, control and monitor extracorporeal blood circulation
2	S5 console	Contains the electronic/power supply pack as well as the fan and batteries for the emergency power supply

Item	Name	Function
3	S5 console table	Supports up to 4 pump housings or units (depending on the type of console)
4	Main switch	Switches the power for the entire S5 system on and off
5	S5 mast retaining flange (left/right)	Side components for supporting the sliding T-bar handles and telescopic masts
6	Push bar	Mounting for the system panel (14)
7 8	Telescope mast with Infusion rack	Mounting for additional equipment
9	Telescope mast, movable with infusion rack	Mounting for disposable items/devices
10	Horizontal mast	Stabilizes the mast system
11	Crossbar for movable mast	Permanently mounted on the back of the console for supporting the movable telescope mast
12 13	Console casters with Parking brakes	Transporting the S5 system
14	S5 system panel	Display and control modules, available in 3, 4 (standard), 5 or 6 module slots
15	S5 electronics and power (E/P) pack	System connection panel (shown with cover closed) for connecting power supply, pumps, devices, etc.
16	S5 roller pump	Available as single or double pump configuration, pumps blood through the CPB circuit
17	S5 double roller pump	

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics (i.e., design, material, performance, energy source) of the modified S5 System are similar to the cleared S5 System (K071318), with minor modifications to the hardware, software and labeling of the device.

Both devices employ mains electricity (AC-powered) console with roller pumps, centrifugal pumps, control panels, accessories and sensory equipment to provide mechanical circulatory support during open-heart surgery.
The following are the technological differences between the subject and predicate devices:

- The Blood Level Sensor has been changed to improve electromagnetic compatibility. The sensor holder and holder pads were modified to accommodate the new sensor.
- Modifications to the graphical user interface were made to introduce new icons.

PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of the modified S5 System to the cleared S5 System.

In accordance with 21 CFR 820.30, LivaNova Deutschland GmbH. has conducted the following verification and validation testing of the S5 System design modifications to ensure that it can provide all the capabilities necessary to operate safely and effectively and that unchanged functions of the device continue to operate as intended:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Performance testing
- Software verification and validation
- Human Factors testing
- Mechanical testing of the modified Sensor Holder
- Performance testing of shipping containers

In support of the determination of substantial equivalence of the modified S5 System to the cleared S5 System, the following recognized Standards have been complied with:

Standard	Title	FDA recognition number
IEC 60601-1 2005 A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2 Edition 4.0 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 62366-1 Edition 1.0 2015	Medical devices — Part 1: Application of usability engineering to medical devices	5-114
60601-1-8:2006 and A1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76
IEC 62304 Edition 1.1 2015	Medical device software — Software life cycle processes	13-79
ISO 14971 Third Edition 2019	Application of risk management to medical devices	5-125

SUMMARY

The modified S5 System is as safe and effective as the cleared S5 System. The modified S5 System has the same intended use and indications, similar technological characteristics, and the same principles of operation as its predicate device. The minor technological differences between the cleared and modified device do not raise different questions of safety or effectiveness. Performance and validation data demonstrate that the subject S5 System is as safe and effective as the predicate device. Thus, the modified S5 System is substantially equivalent to its predicate.