April 1, 2021

Century HLM, LLC
℅ Vaibhav Rajal
Official Correspondent for Century HLM, Inc.
mdi Consultants,Inc.
55 Northern Blvd.
Suite 200
Great Neck, New York 11021

Re: K202125
Trade/Device Name: Century Perfusion System
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary bypass heart-lung machine console
Regulatory Class: Class II
Product Code: DTQ

Dear Vaibhav Rajal:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 7, 2021. Specifically, FDA is updating this SE Letter to correct the typo in the title for Vaibhav Rajal, Official Correspondent for Century HLM, Inc., as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Fernando Aguel, OHT2: Office of Cardiovascular Devices, 301-796-6326, Fernando.Aguel@fda.hhs.gov.

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

March 7, 2021

Century HLM, LLC
% Vaibhav Rajal
Officer Correspondenr for Century HLM, Inc.
mdi Consultants,Inc.
55 Northern Blvd.
Suite 200
Great Neck, New York 11021

Re: K202125
Trade/Device Name: Century Perfusion System
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: February 2, 2021
Received: February 5, 2021

Dear Vaibhav Rajal:

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,

Fernando Aguel -S

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)*

K202125

Device Name
Century Perfusion System

Indications for Use *(Describe)*
The Century Perfusion 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.

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510(k) SUMMARY

The assigned 5l0(k) number is: K202125

Submitter's Identification:

Submitter's Name and Address:	Century HLM, LLC 3110 N. Oakland, STE 101 Mesa, AZ 85215 USA
Name of Contact Person:	Jeff Poland
Phone Number:	1-314-497-5232
Fax Number:	1-314- 787-1580
Email:	jeff@centuryheartlung.com
Establishment registration #	3001589655
Date Summary Prepared:	July 29, 2020
Date Summary Revised to add reference Predicate:	December 2, 2020

Name of the Device:

Trade Name:	Century Perfusion System
Common/Generic Name:	Heart Lung Machine
Regulation Name:	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4220
Product Code:	DTQ
Regulatory Class:	Class II

Information for the 510(k) Cleared Device (Predicate Device):

Stöckert S5 System (K060053) currently marketed by LivaNova

Information for the 510(k) Cleared Device (Reference Predicate Device):

Cobe Century Perfusion Pump (K960974) currently marketed by Century HLM, LLC (Submitter).

Device Description:

The Century Perfusion System is a modular system, like the Stöckert S5 System, consisting of a console base with peristaltic pumps, monitors, displays, controls, and user interfaces.

Indications for Use:

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

Comparison to the 510(k) Cleared Devices (Predicate Devices):

The Century Perfusion System utilizes the same Stöckert peristaltic pump head used by the Stöckert S5 System and by the Cobe Century Perfusion Pump (Century has an indefinite license for the Stöckert peristaltic pump head obtained by Cobe circa 1980). The Century Perfusion Pump (K960974) remains unchanged with the exceptions of label improvements, non RoHS compliant components exchanged to the RoHS compliant version, and electrical improvements to meet current regulations. The Century Console Base includes a UPS battery backup system and computer components to support monitors, displays, controls, and user interfaces like the Stöckert S5 System. Perfusion safety devices include user selected alarms for pressure, temperature, air and level detectors like the Stöckert S5 System.

The Century Perfusion System has been compared to the Stöckert S5 System as a predicate device for substantial equivalence and to the Cobe Century Perfusion Pump as a reference predicate device for substantial equivalence . A table comparing the Century Perfusion System to the Stöckert S5 System is provided below and a table comparing the Century Perfusion Pump to the Cobe Century Perfusion Pump follows the Century Perfusion System to the Stöckert S5 System table below:

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Indications for use	The Century Perfusion System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.	The Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.	SE
Device description	The Century Perfusion System is a modular system consisting of a console base with peristaltic pumps, monitors, displays, controls, and user interfaces.	The Stöckert 55 System is a modular system consisting of a console, various pumps, monitors, displays, controls, and user interfaces.	SE
System components	Roller pumps Console base Sensors UPS and Batteries	Roller pumps Console base Sensors UPS and Batteries	SE

Roller Pump

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Diameter of pump raceway	150 mm	150 mm	SE
Diameter of occlusion roller	30.5 mm	30.5 mm	SE
Speed range	0 to 250 RPM (clockwise, counterclockwise)	0 to 250 RPM (Bi-directional) (clockwise, counterclockwise)	SE
Deviation in speed accuracy	±2% or ±1 count (whichever is greater) of indicated RPM.	±1% of the terminal value 250 rpm plus ±0.5% of set value	D (1) See below

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Speed deviation in the event of a fault (Runaway/Overspeed fault detection) (Detection of faulty speed from 30 rpm)	During continuous operation: +20% max.; 2 revolutions max. until pump stops	During continuous operation: +15% max.; 2 revolutions max. until pump stops	D (2) See below
Direction of rotation	Clockwise/counterclockwise	Clockwise/counterclockwise	SE
Concentricity: 1. Tubing raceway concentricity (Concentricity about axis of rotation of pump head.) 2. Occlusion symmetry (Difference in distance from the center of the pump head to the outermost point on each tubing roller.) 3. Occlusion rollers (Total runout of roller surface measured from roller axis.)	 0.005 mm (0.0002 inch) 0.025 mm (0.0010 inch) 0.013 mm (0.0005 inch)	 0.03 mm (.0012 inch) 0.03 mm (.0012 inch) 0.015 mm (0.0006 inch)	D (3) See below
Rpm display range	0-250 RPM	0-250 RPM	SE
Resolution	1 rpm	1 rpm	SE

Item	**Subject device:** **Century HLM, LLC** **Century Perfusion System**	**Predicate Device:** **LivaNova, PLC** **Stöckert S5 System** **K060053**	**Substantially Equivalent (SE) or Different (D)**
L/min display range (flow)	1/8" ID…….0 to 0.83 L/min 3/16" ID…..0 to 1.79 L/min 1/4" ID…….0 to 3.12 L/min 5/16" ID…..0 to 4.70 L/min 3/8" ID…….0 to 6.50 L/min 1/2" ID…….0 to 11.2 L/min	1/8" ID…….0 to 0.83 L/min 3/16" ID…..0 to 1.79 L/min 1/4" ID…….0 to 3.12 L/min 5/16" ID…..0 to 4.70 L/min 3/8" ID…….0 to 6.50 L/min 1/2" ID…….0 to 11.2 L/min	SE
Deviation of speed slave pump	Max. 1 percentage point of the flow setting	Max. 1 percentage point of the flow setting	SE
Operating voltage	115 or 230 VAC ± 10%, 50 or 60 Hz (indicated on pump nameplate)	24 V DC	D (4) See below
Power Consumption	160 VA	160 VA	SE
Operating Temperature	+10 °C to +40 °C	+10 °C to +40 °C	SE
Storage Temperature	0°C to +40 °C	0°C to +40 °C	SE
Relative Humidity (Operating and Storing)	30% to 75%	30% to 75%	SE
Physical dimensions: Length Width Height Weight	 56 cm (22.1 inches) 18 cm (7.1 inches) 33 cm (13.0 inches) 26 kg (57 lbs)	 48.5 cm (19.1 inches) 18 cm (7.1 inches) 28.5 cm (11.2 inches) 15 kg (33.1 lbs)	D (5) See below

Console Base

Item	**Subject device:** **Century HLM, LLC** **Century Perfusion System**	**Predicate Device:** **LivaNova, PLC** **Stöckert S5 System** **K060053**	**Substantially Equivalent (SE) or Different (D)**
Height (to the surface of the pump cover)	635 mm	640 mm	D (6) See below
Depth	587 mm	600 mm	D (6) See below
Width (incl. push bars) 4 position 5 position	 965 mm 1146 mm	 890 mm 1073 mm	D (6) See below
Weight 4 position 5 position	 110.3 kg 115.9 kg	 86.3 kg 89.5 kg	D (7) See below
Operating Temperature	+10 °C to +40 °C	+10 °C to +40 °C	SE
Storage Temperature	0 °C to +40 °C	0 °C to +40 °C	SE
Relative Humidity (Operating and Storing)	 30% to 75%	 30% to 75%	SE
Telescope masts *Height (from floor)* in lowest configuration (*Century has a single configuration*) in highest configuration Diameter (fixed part)	 1520 mm min. 2120 mm max. Ø 31.88 mm	 1230 mm min. 1840 mm max. 1520 mm min. 2120 mm max. Ø 33 mm	D (8) See below

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Movable base mast *Height (from floor)* Diameter (fixed part)	 1520 mm min. 2120 mm max. Ø 31.88 mm	 1520 mm min. 2120 mm max. Ø 33 mm	SE
Horizontal mast *Length* 4 position 5 position Diameter	 907 mm 1088 mm Ø 31.88 mm	 896 mm 1081 mm Ø 25 mm	D (9) See below
Maximum total load on mast system	 45 kg	 45 kg	SE
Maximum total load on a mast	 20 kg	 20 kg	SE
Maximum load on the infusion rack	 5 kg	 5 kg	SE
System display panel Height Width Depth (without mast holder) Weight (without mast holder) Operating voltage Power consumption Pixel Failure Class	 307 mm 400 mm 59 mm 6.53 kg 24 V 30 W Conformity with Pixel Failure Class III	(S5 6 slot display panel) 475 mm 375 mm 94 mm 7 kg (without display modules) 24 V 45 W Conformity with Pixel Failure Class III	D (10) See below

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Cardioplegia volume control Setting range Accuracy of Dosage	 0 to 2 Liters ±10%, min. tolerance ±20 ml	 0 to 2 Liters ±10%, min. tolerance ±20 ml	SE
Timer counting range	0-999 hours 59 min 59 sec	0-999 min 59 sec	D (11) See below
Input voltages	115 V~; 60 Hz 230 V~; 50/60 Hz	100 V~ to240 V~; 50/60 Hz	D (12) See below
Permissible mains voltage fluctuation	±10%	±10%	SE
Maximum power consumption (standard equipment)	1000 W	1000 W	SE
Mains power protection Circuit breaker:	 10 A nominal trip current	 10 A nominal trip current	SE
Circuit breakers:	Circuit breaker for pumps: 2.5 A in 115 VAC Pump modules 1.5 A in 230 VAC Pump modules Circuit breaker (for auxiliary outlets): 2.5 A @ 115 VAC 1.5 A @ 230 VAC	Circuit breaker for system slots: F1-F12 slots (pumps & devices) 10 A each F13 (sensor module) 10 A (automatic)	D (13) See below
Serial interface Baud rate Word length Parity Stop bits Time grid (interval of the data sent by perfusion system)	 115200 8 bit None 1 1 second	 9600 (fixed) 7 bit None 1 10 seconds	D (14) See below)

UPS and Batteries

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
***Output voltage*:** Nominal voltage Minimum voltage Maximum voltage	 48 V 42.5 V 54.8 V	 24 V 19 V 32 V	D (15) See below)
Output power: Nominal output power Capacity of new batteries Fuse protection of batteries	 400 W 22 Ah 30 A	 400 W 17 Ah 40 A	D (16) See below)
Operating time of UPS: At 400 W output power At 160 W output power Charging time	 112 minutes (115 V) 116 minutes (230V) 297 minutes (115 V) 273 minutes (230V) 15-18 hours	 20 minutes 90 minutes 12-15 hours	D (17) See below)
Discharger: Input voltage	 Not Required	 24 V DC	D (18) See below)

Sensors

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Level Maximum polycarbonate wall thickness at sensor position Tolerance for triggering the pump action (response of the level sensor)	6 mm ±5 mm	3 mm ±10 mm	D (19) See below)
Air Alarm limit 3/8 sensor Alarm limit 1/4 sensor	0.087 cm^3 (Ø 5.5 mm) air volume 0.022 cm^3 (Ø 3.5 mm) air volume	0.144 cm^3 (Ø 6.5 mm) air volume "Large" 0.065 cm^3 (Ø 5.0 mm) air volume "Medium" 0.034 cm^3 (Ø 4.0 mm) air volume "Small" 0.034 cm^3 (Ø 4.0 mm) air volume	D (20) See below)

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053	Substantially Equivalent (SE) or Different (D)
Pressure Measurement range Resolution Accuracy Zero point adjustment range Gain adjustment range (matching) Input resistance Output voltage to pressure transducer	 -200 mmHg to +800 mmHg 1 mmHg ±5 mmHg ±100 mmHg Not required 100 kΩ <10 V	 -200 mmHg to +800 mmHg 1 mmHg ±5 mmHg ±100 mmHg ±20% 100 kΩ <10 V	D (21) See below)
Temperature Measurement range Resolution Accuracy (without sensors)	 0 °C to 50 °C 0.1 °C 0.0 °C – 25 °C ± 0.2 °C 25.0 °C – 45 °C ± 0.1 °C 45.0 °C – 50.0 °C ± 0.2 °C	 0 °C to 50 °C 0.1 °C 0.0 °C – 25 °C ± 0.2 °C 25.0 °C – 45 °C ± 0.1 °C 45.0 °C – 50.0 °C ± 0.2 °C	SE

Classifications

Item	**Subject device:** **Century HLM, LLC** **Century Perfusion System**	**Predicate Device:** **LivaNova, PLC** **Stöckert S5 System** **K060053**	**Substantially Equivalent (SE) or Different (D)**
Type of Electric Shock Protection	Class 1	Class 1	SE
Degree of Electric Shock Protection to applied parts	Type B	Type B	SE
Degree of Protection Against Harmful Ingress of water or particulate matter	IPX1	IPX1	SE
Method of Sterilization or Disinfection	Not Applicable	Not Applicable	SE
Degree of Safety in the Presence of Flammable Anesthetic Mixtures	Not suitable for use in the presence of a flammable anesthetic mixtures	Must not be used in the presence of explosive substances	SE

The major difference between the subject device Century Perfusion System and the predicate device Stöckert S5 System is the ability of the subject device Century Perfusion System's modular Century Perfusion Pump (roller pump) to operate independently of the Century Perfusion System Console Base. A significant difference between the subject device Century Perfusion System and the predicate device Stöckert S5 System is the subject device Century Perfusion System's increased UPS battery backup capacity.

The Indications for Use statement of the subject device is identical to the predicate device. Other differences between the devices are:

1. Deviation in speed accuracy

To compare "deviation in speed accuracy" between the subject device Century Perfusion System roller pump and the predicate device Stöckert S5 System roller pump, a range of the most common settings used in cardiopulmonary bypass were compared. The most common settings for the most critical roller pump (arterial) are between 4 and 5 LPM and the tubing used in an arterial roller pump is most often 1/2 inch ID but may also be 3/8 inch ID. The most common settings for the second most critical roller pump (cardioplegia) are between 0.2 LPM and 0.3 LPM and the tubing most often used is a combination of 1/4 inch ID and 1/8 inch ID tubing to produce a 4:1 ratio of cardioplegia solution. The most common settings for less critical Vent and Suction roller pumps are 50 RPM to 100 RPM and the tubing most often used is 1/4 inch ID tubing. The comparison table below illustrates a slightly better deviation in speed accuracy range for the subject device Century Perfusion System roller pump below 187 RPM and a slightly better deviation in speed accuracy range for the predicate device Stöckert S5 System roller pump above 187 RPM. The deviation in speed accuracy range difference does not affect the subject device's safety, effectiveness, or performance.

1/2" ID tubing
4 LPM = approx. 90 RPM
5 LPM = approx. 113 RPM

3/8" ID tubing
4 LPM = approx. 152 RPM
5 LPM = approx. 187 RPM

1/4" and 1/8" ID tubing
0.1 LPM = approx. 13 RPM
0.2 LPM = approx. 20 RPM

1/4" ID tubing (Vents and Suctions)
50 RPM
100RPM

Deviation in Speed Accuracy Table Using Most Common Settings

Item	Subject device: Century HLM, LLC Century Perfusion System	Predicate Device: LivaNova, PLC Stöckert S5 System K060053
Deviation in speed accuracy at:	±2% or ±1 count (whichever is greater) of indicated RPM.	±1% of the terminal value 250 rpm plus ±0.5% of set value
90 RPM	88.2 to 91.8	87.05 to 92.95
113 RPM	110.74 to 115.26	109.94 to 116.07
152 RPM	148.96 to 155.04	148.74 to 155.26
187 RPM	183.26 to 190.74	183.57 to 190.44
13 RPM	12 to 14	10.44 to 15.57
20 RPM	19 to 21	17.4 to 22.6
50 RPM	49 to 51	47.25 to 52.75
100 RPM	98 to 102	97 to 103

2. Speed deviation in the event of a fault

Also referred to as "Runaway Fault" in LivaNova/Sorin S5 manuals and "Overspeed Detection" in Century manuals, this detection and mitigation was developed to address the phenomenon commonly known as "Runaway pump". Runaway pump is characterized by a rapid acceleration to the maximum pump speed with complete loss of speed control over the affected roller pump. Rapid starting or stopping of the roller pump without tubing in the pump head may trigger a false Runaway pump fault. Manually turning the roller head during loading or unloading of tubing in the roller pump head may also trigger a false Runaway pump fault. Runaway pump detection and mitigation occurs at a 15% increase over the displayed RPM in the predicate device Stöckert S5 System roller pump and at a 20% increase over the displayed RPM in the subject device Century Perfusion System roller pump. The Century Perfusion System roller pump Overspeed Detection at a 20% increase over the displayed RPM lessens the occurrence of false or unintended Runaway pump triggers without affecting its ability to detect a rapid acceleration to the maximum pump speed. This difference does not affect the subject device's safety, effectiveness, or performance.

3. Concentricity

The subject device Century Perfusion System roller pump demonstrates a slight improvement in concentricity compared to the predicate device Stöckert S5 System roller pump. The improved concentricity specifications of the subject device Century Perfusion System roller pump does not affect the subject device's safety or effectiveness and may improve performance.

4. Operating voltage (roller pump)

The subject device Century Perfusion System roller pump requires a 115 or 230 VAC ± 10%, 50 or 60 Hz electrical supply input and each Century module contains its own

internal power supply and transformer to convert the AC input to 24 V DC, whereas the predicate device Stöckert S5 System roller pump requires 24 V DC from a power supply and transformer in the Stöckert S5 System Console base. The subject device roller pump is capable of operating independently of its Century Perfusion System Console base in emergency situations due to failures in the Console base whereas the predicate device Stöckert S5 System roller pump is incapable of operating independently of its Stöckert S5 System Console base as it requires 24 V DC from a power supply and transformer in the Stöckert S5 System Console. This difference does not affect the subject device's performance or effectiveness and may increase the subject device's safety in Console base failure situations.

5. Physical dimensions (roller pump)

The subject device Century Perfusion System modular roller pump physical dimensions are larger than the predicate device Stöckert S5 System modular roller pump physical dimensions to accommodate the subject device's inclusion of a dedicated power supply and transformer as discussed in difference number 4 above. This does not affect the subject device's safety, effectiveness, or performance.

6. Physical dimensions (Console Base)

The subject device Century Perfusion System Console Base physical dimensions are slightly different than the predicate device Stöckert S5 System. The slight differences are attributed to design differences. The slight differences in physical dimensions does not affect the subject device's safety, effectiveness, or performance.

7. Weight (Console Base)

The subject device Century Perfusion System's 4 position Console Base weight is 24Kg heavier than the predicate device Stöckert S5 System's 4 position Console Base and the subject device Century Perfusion System's 5 position Console Base weight is 26.4Kg heavier than the predicate device Stöckert S5 System's 5 position Console Base due to the increased battery backup weight that provides increased emergency UPS battery backup capacity. This difference does not affect the subject device's performance or effectiveness and may increase the subject device's safety during facility power failures.

8. Physical dimensions (Console Base Telescope masts)

The subject device Century Perfusion System's Telescope masts have one configuration for the height from floor whereas the predicate device Stöckert S5 System's Telescope masts have two configurations for the height from floor. The subject device Century Perfusion System's Telescope masts diameter is 1.11 millimeter less than the diameter of the predicate device Stöckert S5 System's Telescope masts. These differences do not affect the subject device's safety, effectiveness, or performance.

9. Horizontal mast (Console Base)

The subject device Century Perfusion System's Horizontal mast lengths are substantially equivalent to the predicate device Stöckert S5 System's Horizontal mast lengths. The

subject device Century Perfusion System's Horizontal mast diameter is 6.89 mm larger than the predicate device Stöckert S5 System's Horizontal mast diameter. This does not affect the subject device's safety, effectiveness, or performance.

10. System display panel (Console Base)

The subject device Century Perfusion System provides a single display panel interface for control and monitoring of timers, pumps, cardioplegia functions, pressures, temperatures, UPS, air detectors and level detectors whereas the predicate device Stöckert S5 System provides a variety of system display panels with 3 to 6 slots to accommodate control and monitoring of timers, pumps, cardioplegia functions, pressures, temperatures, UPS, air detectors and level detectors dependent on which modules are purchased by the user. The subject device Century Perfusion System's single display panel interface is compared to the predicate device Stöckert S5 System's 6 position display panel interface as the 6 position display panel interface is capable of displaying control and monitoring functions substantially equivalent to the Century Perfusion System's single display panel interface. The subject device Century Perfusion System's single display panel interface is smaller in size, weight, and power consumption compared to the functionally substantially equivalent predicate device Stöckert S5 System's 6 position display panel interface. The difference in size, weight, and power consumption does not affect the subject device's safety, effectiveness, or performance.

11. Timer counting range

The subject device Century Perfusion System's timer counting range is significantly higher but functionally equivalent to the predicate device Stöckert S5 System's timer counting range. This difference does not affect the subject device's safety, effectiveness, or performance.

12. Input voltages

The subject device Century Perfusion System uses two models to accommodate the most common global input voltages; 115 V~; 60 Hz and 230 V~; 50/60 Hz whereas the predicate device Stöckert S5 System uses one model to accommodate global input voltages 100 V~ to 240 V~; 50/60 Hz. This difference does not affect the subject device's safety, effectiveness, or performance.

13. Mains Power Protection and Circuit Breaker Protection

The subject device Century Perfusion System modular design is different than the predicate device Stöckert S5 System. The subject device Century Perfusion System's modules are designed to be able to operate independently. Each module includes its own transformer, power supply, and circuit breaker for safe operation independently in the event of a failure in the Century Console Base or in another Century module. The predicate device Stöckert S5 System modules are electrically integrated with the S5 Console Base and the circuit breaker for system slots reflect that. The power protection and circuit breaker design for each device is different but appropriate for each design. This does not affect the subject device's safety, effectiveness, or performance.

14. Serial interface
The subject device Century Perfusion System improves serial interface parameters over the predicate device Stöckert S5 System to allow more data to transfer more frequently. This does not affect the subject device's safety and improves effectiveness and performance of the serial interface.

15. Output voltage (UPS and Batteries)
The subject device Century Perfusion System's UPS battery backup utilizes batteries operating at 48V whereas the predicate device Stöckert S5 System's UPS battery backup utilizes batteries operating at 24V. The subject device Century Perfusion System's UPS battery backup capacity is increased compared to the predicate device Stöckert S5 System's UPS battery backup capacity by operating the UPS battery backup at a nominal voltage of 48VDC compared to the predicate device Stöckert S5 System's UPS battery backup operating at a nominal voltage of 24VDC. This does not affect the subject device's safety, effectiveness, or performance.

16. Output Power (UPS and Batteries)
The subject device Century Perfusion System's fuse protection of UPS batteries is 30 A whereas the predicate device Stöckert S5 System's fuse protection of UPS batteries is 40 A. The subject device Century Perfusion System's UPS battery backup capacity is increased compared to the predicate device Stöckert S5 System's UPS battery backup capacity by operating the UPS battery backup at a nominal voltage of 48VDC compared to the predicate device Stöckert S5 System's UPS battery backup operating at a nominal voltage of 24VDC. The increased operating voltage of the Century Perfusion System UPS battery backup allows for lower UPS battery backup operating current while providing similar operating power. Therefore, the Century Perfusion System UPS battery backup can limit the fault current to a lower level than that of the Stöckert S5 System's UPS battery backup. This does not affect the subject device's safety, effectiveness, or performance.

17. Operating time (UPS and Batteries)
The subject device Century Perfusion System's UPS battery backup operating time is increased compared to the predicate device Stöckert S5 System's UPS battery backup. The subject device Century Perfusion System's UPS battery backup charging time has a wider range compared to the predicate device Stöckert S5 System's UPS battery backup charging time to accommodate the higher capacity of the subject device Century Perfusion System's UPS battery backup. The differences in UPS battery backup operating times and charging times does not affect the subject device's performance or effectiveness and may increase safety in facility power failure situations.

18. Discharger (UPS and Batteries)
The subject device Century Perfusion System's UPS battery backup utilizes a color-coded battery icon that will decrease in length and change color as the UPS battery charge is

depleted whereas the predicate device Stöckert S5 System's UPS battery backup utilizes a percentage of battery backup capacity that decreases as the UPS battery charge is depleted. In order to calibrate the percentage display of battery life remaining the predicate device Stöckert S5 System requires a discharge test utilizing a Discharger on a regular basis. The subject device Century Perfusion System's UPS battery backup color-coded battery icon is based on decreasing battery voltage that does not require a discharge test.

19. Tolerance for triggering the pump action (Level sensor)

The subject device Century Perfusion System's level sensor maximum polycarbonate wall thickness tolerance at the sensor position is 6 mm whereas the predicate device Stöckert S5 System's level sensor maximum polycarbonate wall thickness tolerance at the sensor position is 3 mm. The subject device Century Perfusion System's level sensor tolerance for triggering the pump action (response of the level sensor) is ±5 mm whereas the predicate device Stöckert S5 System's level sensor tolerance for triggering the pump action (response of the level sensor) is ±10 mm. The subject device's maximum polycarbonate wall thickness increased tolerance enables it to work with a wider variety of disposable products and the decreased level sensor triggering tolerance improves triggering accuracy. This does not affect the subject device's safety and improves the subject device's effectiveness and performance.

20. Alarm limit (Air Sensor)

The subject device Century Perfusion System air sensor alarm limit for 3/8" tubing is 0.087 cm3 (Ø 5.5 mm) of air volume whereas the predicate device Stöckert S5 System has three user selectable air sensor alarm limits: 0.144 cm^3 (Ø 6.5 mm) of air volume for "Large", 0.065 cm^3 (Ø 5.0 mm) of air volume for "Medium", and 0.034 cm^3 (Ø 4.0 mm) of air volume for "Small". The subject device Century Perfusion System air sensor alarm limit for 3/8" tubing is substantially equivalent to the predicate device Stöckert S5 System air sensor "Medium" alarm limit for 3/8" tubing. The subject device Century Perfusion System air sensor alarm limit for 1/4" tubing of 0.022 cm^3 (Ø 3.5 mm) air volume is substantially equivalent to the predicate device Stöckert S5 System air sensor alarm limit for 1/4" tubing of 0.034 cm^3 (Ø 4.0 mm) air volume. The subject device Century Perfusion System air sensor's function to detect air as part of the protection system against harmful air delivery is substantially equivalent to the predicate device Stöckert S5 System.

21. Gain adjustment range (Pressure sensor)

The subject device Century Perfusion System does not require a user adjustable gain for the pressure sensor whereas the predicate device Stöckert S5 System does require a user adjustable gain for the pressure sensor. To determine that no user adjustable gain for the pressure sensor is required for the subject device Century Perfusion System to meet substantial equivalence to the predicate device Stöckert S5 System, 32 combinations of pressure sensors and pressure channels on the Century Perfusion System device were tested. These pressure measurements were taken across six

different pressures (-200, 100, 200, 400, 600 and 800 mmHg) across the range of acceptable pressures as noted in the Century Perfusion System documentation. The pressure was individually verified with a calibrated pressure meter, Model HDM97 BOH, SN3628310103002225, in addition to being read by the device with the result recorded. A two-sided K-factor with 90% confidence for 90% of the population was calculated to determine the upper and lower bound for each pressure setting. The resulting bounds were shown to be within the ± 5mmHg accuracy set forth by the predicate device Stöckert S5 System. This difference does not affect the subject device's safety, effectiveness, or performance.

Item	Subject device: Century HLM, LLC Century Perfusion Pump	Predicate Device: Century HLM, LLC COBE Century Perfusion Pump K960974	Substantially Equivalent (SE) or Different (D)
Indications for use	The Century Perfusion Pump is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.	The COBE Century Perfusion Pump is intended for use in cardiopulmonary surgical procedures requiring pumping of fluids in an extracorporeal circuit for periods up to 6 hours.	SE
Device description	The Century Perfusion Pump is the principle component of the Century Perfusion System. It is a peristaltic-type roller pump that functions by tube-occluding rollers that move along a piece of tubing. As the pump head rotates, the rollers draw fluid through the tubing. Pumped fluids are contained within the tubing and have no contact with the pump. The pump has positive displacement over a wide range of flow rates and delivery pressures.	The COBE Century Perfusion Pump is the principle component of the COBE Century Perfusion System. It is a peristaltic-type roller pump that functions by tube-occluding rollers that move along a piece of tubing. As the pump head rotates, the rollers draw fluid through the tubing. Pumped fluids are contained within the tubing and have no contact with the pump. The pump has positive displacement over a wide range of flow rates and delivery pressures.	SE
Pump components	A front panel containing displays and operational switches. A pump head with the roller pump mechanism and shields. A chassis containing control cards, a power supply, and connectors for external devices.	A front panel containing displays and operational switches. A pump head with the roller pump mechanism and shields. A chassis containing control cards, a power supply, and connectors for external devices.	SE

Roller Pump

Item	**Subject device:** **Century HLM, LLC** **Century Perfusion Pump**	**Predicate Device:** **Century HLM, LLC** **COBE Century Perfusion Pump** **K960974**	**Substantially Equivalent (SE) or Different (D)**
Diameter of pump raceway	150 mm	150 mm	SE
Diameter of occlusion roller	30.5 mm	30.5 mm	SE
Speed range	0 to 250 RPM (clockwise, counterclockwise)	0 to 250 RPM (clockwise, counterclockwise)	SE
Deviation in speed accuracy	±2% or ±1 count (whichever is greater) of indicated RPM.	±2% or ±1 count (whichever is greater) of indicated RPM.	SE
Speed deviation in the event of a fault (Runaway/Overspeed fault detection) (Detection of faulty speed from 30 rpm)	During continuous operation: +20% max.; 2 revolutions max. until pump stops	During continuous operation: +20% max.; 2 revolutions max. until pump stops	SE
Direction of rotation	Clockwise/counterclockwise	Clockwise/counterclockwise	SE

Item	Subject device: Century HLM, LLC Century Perfusion Pump	Predicate Device: Century HLM, LLC COBE Century Perfusion Pump K960974	Substantially Equivalent (SE) or Different (D)
Concentricity: 1. Tubing raceway concentricity (Concentricity about axis of rotation of pump head.) 2. Occlusion symmetry (Difference in distance from the center of the pump head to the outermost point on each tubing roller.) 3. Occlusion rollers (Total runout of roller surface measured from roller axis.)	 0.005 mm (0.0002 inch) 0.025 mm (0.0010 inch) 0.013 mm (0.0005 inch)	 0.095 mm (0.0037 inch) 0.05 mm (0.0020 inch) 0.015 mm (0.0006 inch)	D (1) See below
Rpm display range	0-250 RPM	0-250 RPM	SE
Resolution	1 rpm	1 rpm	SE
L/min display range (flow)	1/8” ID…….0 to 0.83 L/min 3/16” ID…..0 to 1.79 L/min 1/4” ID…….0 to 3.12 L/min 5/16” ID…..0 to 4.70 L/min 3/8” ID…….0 to 6.50 L/min 1/2” ID…….0 to 11.2 L/min	1/8” ID…….0 to 0.83 L/min 3/16” ID…..0 to 1.79 L/min 1/4” ID…….0 to 3.12 L/min 5/16” ID…..0 to 4.70 L/min 3/8” ID…….0 to 6.50 L/min 1/2” ID…….0 to 11.2 L/min	SE

Item	**Subject device:** **Century HLM, LLC** **Century Perfusion Pump**	**Predicate Device:** **Century HLM, LLC** **COBE Century Perfusion Pump** **K960974**	**Substantially Equivalent (SE) or Different (D)**
Deviation of speed slave pump	Max. 1 percentage point of the flow setting	Max. 1 percentage point of the flow setting	SE
Operating voltage	115 or 230 VAC ± 10%, 50 or 60 Hz (indicated on pump nameplate)	115 or 230 VAC ± 10%, 50 or 60 Hz (indicated on pump nameplate)	SE
Power Consumption	160 VA	150 VA (nominal)	D (2) See below
Operating Temperature	+10 °C to +40 °C	+16 °C to +38 °C	D (3) See below
Storage Temperature	0°C to +40 °C	–18 °C to 55 °C	D (4) See below
Relative Humidity (Operating and Storing)	30% to 75%	0 to 95% Noncondensing	D (5) See below
Physical dimensions: Length Width Height Weight	 56 cm (22.1 inches) 18 cm (7.1 inches) 33 cm (13.0 inches) 26 kg (57 lbs)	 56 cm (22.1 inches) 18 cm (7.1 inches) 33 cm (13.0 inches) 26 kg (57 lbs)	SE

There are no major differences between the subject device Century Perfusion Pump and the predicate device COBE Century Perfusion Pump K960974. The Century Perfusion Pump remains largely unchanged with the exceptions of increased electrical grounding improvements to meet updated ESD regulations, non RoHS compliant components exchanged to the RoHS compliant version from the same manufacturer, and label improvements.

The Indications for Use statement of the subject device is substantially equivalent to the predicate device. Other differences between the devices are:

1. Concentricity
The subject device Century Perfusion Pump demonstrates improvement in concentricity compared to the predicate device COBE Century Perfusion Pump (K960974). The improved concentricity specifications of the subject device Century Perfusion Pump does not affect the subject device's safety or effectiveness and may improve performance.

2. Power Consumption
Power consumption varies by pump speed. The increased nominal power consumption calculated for the subject device Century Perfusion Pump does not affect the subject device's safety, effectiveness, or performance.

3. Operating Temperature
Operating temperature testing parameters for the subject device Century Perfusion Pump were chosen based on operating temperature parameters of the primary predicate device Stöckert S5 System. The wider operating temperature range of the subject device Century Perfusion Pump does not affect the subject device's safety, effectiveness, or performance.

4. Storage Temperature
Storage temperature testing parameters for the subject device Century Perfusion Pump were chosen based on storage temperature parameters of the primary predicate device Stöckert S5 System. The narrower storage temperature range of the subject device Century Perfusion Pump does not affect the subject device's safety, effectiveness, or performance.

5. **Relative Humidity**
Relative humidity testing parameters for the subject device Century Perfusion Pump were chosen based on relative humidity parameters of the primary predicate device Stöckert S5 System. The narrower relative humidity range of the subject device Century Perfusion Pump does not affect the subject device's safety, effectiveness, or performance.

Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The Century Perfusion System has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the Stöckert S5 System. The essential critical component in both the Century Perfusion System and the Stöckert S5 System is the Stöckert peristaltic pump head. The Century Perfusion System and the Stöckert S5 System provide the same perfusion safety devices including user selected alarms for pressure, temperature, air bubble and reservoir level detectors.

Testing to the following standard was conducted by Element Materials Technology to prove the safety and effectiveness of the Century Perfusion System regarding electromagnetic disturbances:

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility

Testing to the following standards was conducted by Intertek to prove the safety and effectiveness of the Century Perfusion System:

- IEC 60601-1 Edition 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 60601-1-8:2010 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: Alarms
- IEC 62304:2015 Medical device software - Software life-cycle processes.
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.

None of the testing demonstrated any design characteristics that violated the above requirements or resulted in any safety hazards. It was our conclusion that

the Century Perfusion System met all relevant requirements of the aforementioned tests.

Clinical Tests Performed:

No clinical tests performed. Roller pumps have been used for cardiopulmonary bypass procedures since the 1950s. The use and risks have been studied extensively. Information analyzed that was reported to the FDA via the MAUDE database was found to be representative of the hazards and risks that have been addressed both in the ISO 14971 Century Perfusion System Risk Management Document and the Instructions for Use. Per the Instructions for Use, this device is to be used only when continuously attended by a properly trained perfusionist. This means any incident would happen in the presence of a person trained on how to respond in the appropriate manner. These factors minimize the risks associated with the use of the Century Perfusion System. Journal articles analyzed show that the use of cardiopulmonary bypass pumps for extra-corporeal oxygenation have been studied and analyzed extensively, either as the main topic of the article / study (in the analysis of 93 previously performed studies, for example) or as an adjunct to more specific discussions related to very specific conditions or pharmaceutical agents administered during this type of surgical procedure (such as an article relating to the inflammatory response of the patient).

Biocompatibility Testing

The Century Perfusion System does not come into contact with the patient. Therefore biocompatibility testing is not included as part of this premarket notification.

Software information:

In line with current FDA policy, and the 11/05 FDA "Guidance for the Content of Premarket Submissions for Software Contained in the Medical Devices", Century is submitting software validation documentation covering a "major level of software concern" for the Century HLM System software. In addition to the required sections of the FDA Guidance, the software development has followed the processes set for in the latest version of IEC 62304 with a Software Safety Classification of C. A third party has also conducted an independent summative usability study as further evidence that the system meets the user needs.

Our device utilizes two dedicated tools for the development of the software. The IDEC display has its own development tool for creation of the Graphical User Interface portion. This tool does not require any additional libraries or binaries in order to generate the output file that is downloaded to the IDEC display. The

Panasonic PLC also has its own development tool for the creation of ladder logic 'code' that runs the system controls for air detect sensors, level sensors, pressure sensors, temperature sensors, automatic pump speed reduction, and cardioplegia delivery. This ladder logic does not directly control the pump speeds as they are manually set by the user via knobs on the front of each pump device. In conclusion, the system does not require the use of off-the-shelf software in the traditional sense.

Conclusions:

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to the predicate device, the Century Perfusion System has been shown to be substantially equivalent to the legally marketed predicate devices.