September 21, 2023

S.A.L.F. spa
% Joyce St. Germain
Regulatory Consultant
The 510k Consulting, LLC
1449 Springleaf Drive
Ormond Beach, Florida 32174

Re: K230193
Trade/Device Name: Servator P Plus SALF Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN
Dated: January 24, 2023
Received: January 24, 2023

Dear Joyce St. Germain:

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,

Gema Gonzalez -S

Gema Gonzalez
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K230193

Device Name
Servator P Plus SALF Solution

Indications for Use *(Describe)*
Servator P Plus SALF Solution is indicated for the flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

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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826 The 510k Consulting LLC

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Traditional 510(k) Summary K230193

I. Submitter

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Date Prepared: January 24, 2023

Preparer/Consultant/Contact

The 510k Consulting, LLC

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Ormond Beach, FL 32174
904-477-3203
Primary Contact: Joyce St. Germain, Regulatory Consultant, joyce510kfda@gmail.com

II. Device

Trade Name:	Servator P Plus SALF Solution
Common Name:	Organ perfusion and preservation solution
Classification Name:	System, Perfusion, Kidney
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Review Panel:	Gastroenterology/Urology
Regulation Class:	II
Product Code:	KDN
Submission Type:	510(k)

III. Predicate Device

510(k) Number:	K170826
Date Cleared:	June 22, 2018

Manufacturer:	XVIVO Perfusion AB
Trade Name:	Perfadex Plus
Common Name:	Solution for lung preservation
Classification Name:	System, Perfusion, Kidney
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Review Panel:	Gastroenterology/Urology
Regulatory Class:	II
Product Code:	KDN

This predicate has not been subject to a design-related recall.

IV. Device Description

Servator P Plus SALF Solution is an extracellular electrolyte solution containing Dextran 40. The solution is pre-buffered with 2 mM THAM and pre-supplemented with 0.5 mM CaCl2. Servator P Plus is used for rapid cooling, perfusion, and cold static storage of lungs in connection with transplantation. Administration of the solution at the recommended temperatures will effectively cool the lung to reduce its metabolic requirements. The colloid component, Dextran 40 counteracts tissue oedema and protects the microvasculature against post-ischemic reperfusion injury. Calcium is important to maintain endothelial and epithelial cell integrity and endothelial contractility. The device is buffered with THAM to achieve a physiological ph. that enables safe preservation of lungs for up to 12 hours depending on status of the lung during retrieval. The intended patient population is adult patients in need of a lung transplantation.

V. Indications for Use

Servator P Plus SALF Solution is indicated for the flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

Note: The Indication for Use statement is equivalent to the predicate device.

Intended Use: Organ perfusion and preservation solution.

VI. Comparison Technological Characteristics with the Predicate Device

Physical properties: The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 7.2 to 7.6. Sterile non-pyrogenic solution for organ preservation of Class II. The solution is clear, colorless, or slightly yellow.

Feature	Subject Servator P Plus SALF Solution	Predicate Perfadex Plus K170826
Indications For Use	Servator P Plus SALF Solution is indicated for the flushing, cold static storage, and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.	Perfadex Plus is indicated for the flushing static cold storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.
Intended Use	Used for organ perfusion and hypothermic preservation.	Used for organ perfusion and hypothermic preservation.
Regulation Number	21 CFR 878.5880	21 CFR 878.5880
Product Code	KDN	KDN
Regulation Name	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories
Device Description	Servator P Plus SALF Solution is an extracellular electrolyte solution containing Dextran 40. The solution is pre-buffered with 2 mM THAM and pre-supplemented with 0.5 mM CaCl2. Servator P Plus SALF is used for rapid cold static storage of lungs in connection with transplantation. Administration of the solution at the recommended temperatures will effectively cool the lung to reduce its metabolic requirements. The colloid component, Dextran 40 counteracts tissue oedema and protects the microvasculature against post-ischemic reperfusion injury. Calcium is important to maintain endothelial and epithelial cell integrity and endothelial contractility. The device is buffered with THAM to achieve a physiological pH. Servator P Plus SALF enables safe preservation of lungs for up to 12 hours depending on status of the lung during retrieval. The intended patient population is adult patients in need of a lung transplant.	Perfadex Plus is an extracellular electrolyte solution containing Dextran 40. The solution is pre-buffered with 2 mM THAM and presupplemented with 0.5 mM CaCl2. Perfadex Plus is used for rapid cooling, perfusion and cold static storage of lungs in connection with transplantation. Administration of the solution at the recommended temperatures will effectively cool the lung to reduce its metabolic requirements. The colloid component, Dextran 40 counteracts tissue oedema and protects the microvasculature against post-ischemic reperfusion injury. Calcium is important to maintain endothelial and epithelial cell integrity and endothelial contractility. The device is buffered with THAM to achieve a physiological pH. PERFADEX® Plus enables safe preservation of lungs for up to 12 hours depending of status of the lung during retrieval. The intended patient population is adult patients in need of a lung transplantation.
Meets UNOS Policy	Yes	Yes

Container	PVC free bags	PVC free bags
pH	7.20 – 7.60	7.20 – 7.60
Osmolality	295 mOsm/kg	295 mOsm/kg
Bag Material	PVC free material	PVC free material
Protective Overlap Bag	Yes	Yes
Particulate Matter and Biocompatibility	Particle Counts less than limits for Large Volume Injections per USP <788>; Biocompatible per ISO 10993-1 battery of tests for Externally Communicating Blood Path Indirect Contact for prolonged periods >24 hours.	Particle Counts less than limits for Large Volume Injections per USP <788>; Biocompatible per ISO 10993-1 battery of tests for Externally Communicating Blood Path Indirect Contact for prolonged periods >24 hours.
Bag Connections	1 flip off, 1 needle point	Click system – connector that clicks onto the port rather than inserting a spike into the rubber stopper.
Sterilization	Sterilization processes validated. According to either ISO 17665 or USP Section <1211>	Sterilization processes validated. According to either ISO 17665 or USP Section <1211>
Sterilization Method	Steam	Steam
Nominal Volume	1000 mL bags and 3000ml bags	1000 mL bags
Storage Temperature and Shelf-Life	Store 2.0-25.0°C. Do not freeze. Store in its original container. Do not remove the overwrap until immediately before use. The device is sterile and disposable. The solution must be used for one single uninterrupted administration and any residue must be discarded to avoid risk of contamination due to loss of sterility. Do not use if the solution is frozen.	Store 2.0-25.0°C. Do not freeze. Store in its original container. Do not remove the overwrap until immediately before use. The device is sterile and disposable. The solution must be used for one single uninterrupted administration and any residue must be discarded to avoid risk of contamination due to loss of sterility. Do not use if the solution is frozen.

	2 years (24 months) shelf life	2 years (24 months) shelf life
Interaction with Other Medical Technology	**WARNINGS AND PRECAUTIONS FOR USE** Do not use if contamination is evident in the solution. Use only clear solutions in undamaged containers. Servator P Plus is intended for single use only and MUST NOT BE REUSED. Reuse of Servator P Plus is not allowed die to the risk for infection. Do not use Servator P Plus if the use by date has expired. Servator P Plus is not intended for intravenous administration in the human body. Ensure that the Servator P Plus bag is not in direct contact with ice. Do not use the injection port for administration. Servator P Plus is pre-buffered and pe-supplemented with calcium ions. Additional buffer, such as THAM and calcium ions, MUST NOT be added. Do not use a pressure cuff or add external pressure on the Servator P Plus bag since an elevated pressure might introduce damage to the vasculature or the bag might break.	**WARNINGS AND PRECAUTIONS FOR USE** Subject and Predicate descriptions are the same.
Precautions	No additives are necessary as Servator P Plus is pre-buffered and pre-supplemented with calcium ions. The solution should be kept chilled and used within 24 hours after the container is opened. If any other additives are used, chill solution as directed	Subject and Predicate descriptions are the same.

	prior to adding any additives and mix thoroughly immediately prior to use. The use of Servator P Plus cannot improve an already damaged lung. Recovery of healthy lungs under proper conditions is essential. Treatment of children: There is no data on the use of Servator P Plus on children. Pregnancy: There is no data on the use of Servator P Plus during pregnancy. Lactation: It is not known to what extent Servator P Plus passes into breast milk.	

The above comparison shows the subject and predicate devices are equivalent in each attribute/characteristic.

The Servator P Plus SALF Solution and the predicate device are equivalent in composition as listed below. Both solutions are packaged in plastic containers and are supplied sterile.

Composition of Subject and Predicate Devices

NOTE. . . The composition list is identical for the subject and predicate device, therefore; the subject and predicate devices are identical in chemical composition.

Qualitative and quantitative composition.

1000 ml of solution contains:

COMPOSITION					
Dextran 40	50	g	Sodium	138	mmol/l
Glucose monohydrate	1	g	Potassium	6	mmol/l
Potassium chloride	0.4	g	Magnesium	0.8	mmol/l
Sodium chloride	8	g	Glucose	5	mmol/l
Magnesium sulphate heptahydrate	0.201	g	Chlorides	143	mmol/l
Potassium dihydrogen phosphate	0.063	g	Sulphates	0.8	mmol/l
Disodium phosphate dihydrate	0.0576	g	Total Phosphates	0.8	mmol/l
Calcium Chloride dihydrate	0.074	g	Calcium	0.50	mmol/l
THAM	0.24	g	THAM	2.00	mmol/l

Water for injections q.s. to	1000	ml			

Physical properties: The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 7.2 to 7.6. Sterile non-pyrogenic solution for organ preservation of Class II. The solution is clear, colorless, or slightly yellow.

Servator P Plus SALF Solution and the predicate device are solutions packaged in 1-liter bags. The subject device has an additional package of 3-liter bags, as well.

Both the **Servator P Plus SALF Solution** and the predicate devices are supplied sterile.

Not for Direct Injection or Intravenous Use (Single Use Only) Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
The above comparison shows the subject and predicate devices are substantially equivalent in technology characteristics.

The Servator P Plus SALF Solution has equivalent indication for use, intended use, design, materials, packaging, and other technological characteristics to the predicate device.

VII. Performance Data

Non-Clinical Performance Data

The following performance data is provided in support of the substantial equivalence determination. All tests performed are included in this submission.

Biocompatibility… is required for this device. The tests were all performed according to the ISO 10993 series (10993-1, 10993-2, 10993-4, 10993-5, 10993-10, 10993-11, and 10993-12) and the subject device passed all biocompatibility test standards.

Sterilization and Shelf Life . . . is required for the subject device. The Validation of Sterility was performed, and the results passed according to ISO 17655-1. Steam sterilization and storage conditions are the same for the subject and predicate device. Shelf life for the subject and predicate is the same, at 24 months.

Electrical Safety and EMC . . . testing was not applicable for this device.

Software and Risk Management… software is not applicable for this device; however, ISO 14971 was performed for risk.

Performance Testing…was completed as a direct comparison between the subject and predicate device. The chemical comparisons and leachable performance testing in part supported the substantial equivalence of this device to the predicate.

Conclusion

The subject and predicate devices have the same indications for use and the same intended use.

Both devices are substantially equivalent in design, materials, packaging and other technological characteristics and performance.

After analyzing verification of device performance by performance tests included in this submission, it is the conclusion of S.A.L.F., spa that Servator P Plus SALF Solution is equivalent to the predicate and does not raise new questions concerning safety and effectiveness.

The **Servator P Plus SALF Solution** does not raise any questions regarding safety and effectiveness and is equivalent to the predicate device. The non-clinical data supports and demonstrates substantial equivalence.

The conclusion is that **Servator S SALF Solution** warrants a finding of substantial equivalence to the legally marketed Perfadex Plus Solution, K170826 and therefore, should have clearance for premarket activities in the United States.