August 19, 2021

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

Re: K202652
Trade/Device Name: Servator P SALF Solution with THAM
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: July 15, 2021
Received: July 19, 2021

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,

for Carolyn Y. Neuland, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202652

Device Name
Servator P SALF Solution with THAM

Indications for Use *(Describe)*
Servator P SALF Solution with THAM is indicated for flushing, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

The 510k Consulting LLC
Key to success in obtaining your medical device clearance
1449 Springleaf Dr., Ormond Beach, FL 32174
joyce510kfda@gmail.com

510(k) Summary

Submitter/Applicant

S.A.L.F. S.p.A
Via Marconi, 2,
Cenate Sotto, BG, Italy
Phone: +39-035-940097
Contact: Dr. Carmelo Gagliano (Quality Manager) carmelo.gagliano@salfspa.it

Date Prepared: September 4, 2020

Preparer/Consultant

The 510k Consulting, LLC
1449 Springleaf Drive
Ormond Beach, FL 32174

Phone: 904-477-3203
Contact: Joyce St. Germain, Regulatory Consultant, joyce510kfda@gmail.com

Device Classification

Trade/Device Name:	Servator P SALF Solution with THAM
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
Product Code:	KDN
Regulatory Class:	II
510k Review Panel:	Gastroenterology/Urology Panel

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K091989
Date Cleared	October 1, 2010
Submitter:	XVIVO Perfusion AB
Trade Name:	Perfadex® with THAM

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
Product Code:	KDN
Regulatory Class:	II
Medical Specialty:	Gastroenterology/Urology Panel

Indications for Use

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

Intended Use

Organ storage and preservation for transplantation of lungs.

Device Description

Servator P SALF Solution with THAM is a clear to light yellow, single use only, sterile (by steam sterilization) is indicated for the flushing, static cold storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into recipient. The solution is used for organ perfusion and hypothermic preservation. It is an ideal solution for the preservation of lungs.
The solution cooled to 4° to 8° C (39° to 46° F) is used to spray the organ isolated immediately after removal from the donor. The colloidal component Dextran 40 protects in particular micro-vessels from a possible damage caused by the post-ischemic reperfusion, since it prevents pathological leukocyte-endothelial interactions. In addition, Dextran 40 prevents edema and the formation of thrombi.

The primary containers used for the device are:

1) PVC free bags 1000ml, therefore they are free of phthalates. The solution may be used without any point of use filtration.
2) Clear glass bottles 25ml, therefore they are free of phthalates. The solution may be used without any point of use filtration.

Comparison of Technological Characteristics with Predicate

- The indications for use and intended use of the subject and predicate devices are identical.

- The technologies are substantially equivalent as the composition of both solutions are identical.
- The subject and predicate devices are both supplied in bags with overbags for single use.
- The subject and predicate devices are both supplied sterile.
- Tests were performed in order to confirm the equivalence between the subject and predicate devices. The following table compares technological and other characteristics of the subject and predicate device.

Table of Comparison

Technological Comparison

	Subject Device	Predicate Device	Comparison
Device	**Servator P SALF Solution with THAM**	**Perfadex and Perfadex with THAM**	**NA**
Manufacturer	SALF spa, Italy	XVIVO Perfusion AB, Sweden	NA
510(k) Number	NA	K091989	NA
Classification & Product Code	876.5880; KDN	876.5880; KDN	Same
Regulation Name	Isolated Kidney Perfusion and Transport System and Accessories	Isolated Kidney Perfusion and Transport System and Accessories	Same
Device Classification Name	System, Perfusion, Kidney	System, Perfusion, Kidney	Same
Common Name	Solution for lung preservation	Solution for lung preservation	Same
Device Description	Servator P SALF Solution with THAM is a clear to light yellow, single use only, sterile (by steam) is indicated for the flushing, static cold storage and transportation of isolated lungs after removal from the donor in preparation of eventual transplantation into recipient. The solution is used for organ perfusion and hypothermic preservation. It is an ideal solution for the preservation of lungs.	Perfadex® and Perfadex® with TRAM is a clear, sterile, non-pyrogenic, colloid based, lightly buffered so called "extracellular" low potassium dextran solution primarily for rapid cooling, perfusion and storage of lungs in connection with transplantation.	Same

Indication for Use	Servator P SALF Solution with THAM is indicated for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.	Perfadex® Solution for Lung Perfusion is intended for the flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.	Same
Intended Use	Organ storage and preservation for transplantation	Organ storage and preservation for transplantation	Same
Mode of operation	Cold storage	Cold storage	Same
Container/Bag	PVC free bags	PVC free bags	Same
Solution qualitative and quantitative composition	Dextran 40 50g Glucose monohydrate 1g Potassium chloride 0.4g Sodium chloride 8g Magnesium sulfate heptahydrate 0.201g Potassium dihydrogen phosphate 0.063g Disodium phosphate dihydrate 0.0576g Sodium 138 mmol/l Potassium 6 mmol/l Glucose 5 mmol/l Chlorides 142 mmol/l Sulfates 0.8 mmol/l	Dextran 40 50g Glucose monohydrate 1g Potassium chloride 0.4g Sodium chloride 8g Magnesium sulfate heptahydrate 0.201g Potassium dihydrogen phosphate 0.063g Disodium phosphate dihydrate 0.0576g Sodium 138 mmol/l Potassium 6 mmol/l Glucose 5 mmol/l Chlorides 142 mmol/l Sulfates 0.8 mmol/l	Same

	Total Phosphates 0.8 mmol/l Water for injections q.s. to 1000ml	Total Phosphates 0.8 mmol/l Water for injections q.s. to 1000ml	
Meets UNOS Policy	Yes	Yes	Same
Physical Properties	The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 5.3 to 5.5. Sterile pyrogen-free solution for organ preservation of Class II. The solution is clear, colorless or slightly yellow. Before use the pH of the solution should be adjusted to 7.4 by adding a suitable buffer 25 ml of THAM 1mmol/l.	The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 5.3 to 5.5. Sterile pyrogen-free solution for organ preservation of Class II. The solution is clear, colorless or slightly yellow. Before use the pH of the solution should be adjusted to 7.4 by adding a suitable buffer 25 ml of THAM 1mmol/l.	Same
Container	PVC free bags	PVC free bags	Same
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.	Same
Device Standards of Conformity	ISO 10993-4 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 11607-1 ISO 11607-2 ISO 11737-1	ISO 17665 ISO 10993 Series USP <788> USP <1211> Exact test series of predicate device are unknown	Subject device passed according to ISO Standards

	ISO 14971 ISO 15223-1 ISO 17025 ISO 17665-1 USP 39 <71> USP 39 <85> USP 41 <151> USP <1211>		
Protecting Overwrap bag	Yes	Yes	Same
Bag connections	1 flip off, 1 needle point	1 flip off, 1 needle point	Same
Single use only	Yes	Yes	Same
Sterilization	Sterilization processes validated according to ISO 17665 or USP <1211>	Sterilization processes validated according to ISO 17665 or USP <1211>	Same
Sterilization method	Steam	Steam	Same
Nominal value	1000 mL bags + THAM	1000 mL bags + THAM	Same
Shelf Life	24 months	24 months	Same
Storage Temperature	Store below 30°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 below 30°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.	Same

Interaction with other medical technology	Not intended for continuous perfusion. Standard transplantation surgical expertise and techniques are required.	Not intended for continuous perfusion. Standard transplantation surgical expertise and techniques are required.	Same

Test	SALF	Predicate
Temperature of storage of product	<30°C*; Do not freeze	2°-25°C
Temperature of transport	4-8°C	4-8°C
Shelf life	2 years	2 years
Shelf life after reconstitution	24 hours	24 hours

*It is calculated on basis of stability study. The product is stable at 25°C for 2 years and at least 6months at 40°C.

About the storage condition please let me know if we have to restrict the rage from <30°C*; Do notfreeze to 2°-25°C.

The above comparison shows the subject and predicate devices are identical in eachattribute/characteristic.

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

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

The above comparison shows the subject and predicate devices are substantially equivalent in technology characteristics.

The Servator P SALF Solution with THAM have the same indication for use, intended use, design, materials, packaging and other technological characteristics to the predicate device.

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 that are listed in the Table of Comparison above. 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 device is the same at 24 months.

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

Software … was not applicable for this device.

Performance Testing…was completed as a direct comparison between the subject and predicate device. The chemical comparisons and leachable performance testing demonstrated 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 (since they have, in fact, the same chemical composition).

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

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