March 21, 2019

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

Re: K180481
Trade/Device Name: Servator B SALF Solution
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: May 25, 2018
Received: May 31, 2018

Dear Joyce St. Germain:

This letter corrects our substantially equivalent letter of June 29, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180481

Device Name
Servator B SALF Solution

Indications for Use *(Describe)*

Servator B SALF Solution is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and 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.

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

510(k) Summary

Submitter/Applicant

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Date Prepared: June 28, 2018

Preparer/Consultant

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Contact: Joyce St. Germain, Regulatory Consultant
(joyce510kfda@gmail.com)

Device Classification

Trade/Model Names:	Servator B SALF Solution
Common Name:	Organ perfusion and preservation solution
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

Predicate Device

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

510(k) Number:	K091245
Date Cleared	July 17, 2009
Trade Name:	CoStorSol / Brand Name: Belzer UW
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
Product Code:	KDN
Regulatory Class:	II
Medical Specialty:	Gastroenterology/Urology Panel

Indications for Use

Servator B SALF Solution is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

Intended Use

Organ storage and preservation for transplantation.

Device Description

Servator B SALF Solution is a clear to light yellow, single use only, sterile (by steam sterilization) and non-pyrogenic for hypothermic flushing and preservation of organs.

The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and phosphoric compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

The primary containers used for the device are PVC free bags 1000ml and 2000ml; therefore, they are free of phthalates. The bags must be chilled to between 2° and 6° C (36° to 43° F) prior to use. The solution may be used without any point of use filtration.

The **Servator B SALF Solution** is intended for perfusion and flushing donor kidneys, liver and pancreas immediately before or immediately after removal from a dead donor or immediately after removal from a living donor. The solution remains in the organ vessels during hypothermic storage and transportation. **Servator B SALF Solution** is meant for the cold storage of the organ and is not indicated for hypothermic preservation with continuous mechanical perfusion.

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

Table B.1 -- Technological Comparison

	Subject Device	Predicate Device	Comparison
Device	**Servator B SALF**	**CoStorSol®**	**NA**
510k Number	**K180481**	**K091245**	
Manufacturer	S.A.L.F. S.p.A. (Italy)	Preservation Solutions, Inc., WI, USA	NA
Classification & Product Code	876.5880; KDN	876.5880; KDN	Same
Device Classification Name	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories	Same
Device Description	System, Perfusion, Kidney	System, Perfusion, Kidney	Same
Common Name	Organ perfusion and preservation solution	Organ perfusion and preservation solution	Same
Indications for Use	Servator B SALF Solution is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.	CoStorSol® is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.	Same

Intended for Use	Organ storage and preservation for transplantation	Organ storage and preservation for transplantation	Same
Meets UNOS Policy	YES	YES	Same
Material Container/Bag	PVC Free / Bags	PVC Free / Bags	Same
Protecting Overwrap Bag	YES	YES	Same
Single Use Only	YES	YES	Same
Bag Connections	1 flip off, 1 needle point	1 flip off, 1 needle point	Same
Used for Organ Transplants of	Used for kidneys, liver and pancreas	Used for kidneys, liver and pancreas	NA

Product State	Liquid - Solution	Liquid - Solution	Same
Model Numbers	Bag1000ml / SERVB10DMA Bag 2000ml / SERVB20DM	Bag 1000ml / Model # unknown	**Different Model Numbers - due to different manufactures**
Configurations	Box containing 10 bags of 1000ml PVC free. Box containing 5 bags of 2000ml PVC free.	Bags 1000 ml, and carton of 10	**Same, Subject device has additional packaging available**
Sterilization Method	Steam - Sterilization processes validated	Solution is aseptically processed and the tubing used for the	**Different; however both passed according to ISO standards**

		according to ISO 17665-1	aseptic filling is steam sterilized. The bags are gamma sterilized. Sterilization processes were validated according to ISO 17665-1 or USP Section <1211>, as appropriate.	
Sodium Concentration		29 mEq/L	29 mEq/L	Equivalent
Potassium Concentration		125 mEq/L	125 mEq/L	Equivalent
pH		7.4 at 20°C	7.4 at 20°C	Equivalent
Osmolality		320 mOsm/Kg	320 mOsm/Kg	Equivalent
Manufacture Standards of Conformity		ISO 9001:2008 ISO 13485:2003 GMP Certification	Unknown	Subject meets current standards
Shelf Life		24 Months	24 Months	Same
Device Standards of Conformity		Subject device passed according to ISO standards	Unknown	Subject device passed according to ISO standards
ISO Standards		ISO 10993-1 10993-2 10993-4 10993-5 10993-10 10993-11 10993-12 10993-18 ISO 11607-1 11607-2 ISO 11737-1 ISO 14001 ISO 14971 ISO15189	ISO 10993 series ISO 17665 USP <788> USP <1211>	Subject and Predicate passed standardized tests

	ISO15223-1 ISO 17025 ISO 17665-1 ASTM F1980-16 USP <71> USP <85> USP <39> USP <1225>		

The above comparison shows the subject and predicate devices are substantially equivalent in technology characteristics. The differences are highlighted and those differences do not make the subject device any less safe and effective as the predicate device. The differences are due to different manufacturers with different model numbers and the subject device has additional configuration of packaging that the predicate doesn't have.

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 Cytotoxicity, Irritation, System Toxicity and Haemocompatibility tests were all performed of the ISO 10993 series and all are listed above in the Table of Comparison. 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 and ASTM F1980-16. 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 leachables 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 B 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 the safety of the device.

The conclusion is that **Servator B SALF Solution** warrants a finding of substantial equivalence to the legally marketed CoStorSol® by Preservations Solutions, Inc., and therefore, should have clearance for premarket activities in the United States.