December 20, 2021

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

Re: K211842
Trade/Device Name: Servator M SALF Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories
Regulatory Class: II
Product Code: KDL
Dated: December 10, 2021
Received: December 16, 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,

Glenn B. Bell, Ph.D.
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)*
K211842

Device Name
Servator M SALF Solution

Indications for Use *(Describe)*
Servator M SALF Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their 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.

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The 510k Consulting LLC
Key to success in obtaining your medical device clearance
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510(k) Summary K211842

Submitter/Applicant

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Date Prepared: May 28,2021

Preparer/Consultant

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

Device Classification

Trade/Model Names:	Servator M SALF Solution
Submitter:	SALF, S.p.A., Italy
Common Name:	Cold Storage Solution
Classification Name:	System, Perfusion, Kidney, Disposable
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Product Code:	KDL
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:	K121736
Date Cleared	August 16, 2013
Submitter:	Waters Medical Systems, LLC, Rochester, MN
Trade Name:	PERF-GENQ® Pulsatile Perfusion Solution

Common Name:	Cold Storage Solution
Classification Name:	Set, Perfusion, Kidney, Disposable
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Product Code:	KDL
Regulatory Class:	II
Medical Specialty:	Gastroenterology/Urology Panel

Indications for Use

Servator M SALF Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

Intended Use

Organ perfusion and preservation solution.

Device Description

The Servator M SALF is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explained kidneys. This solution has an approximate calculated osmolarity of 300 mOsm/kg, a sodium concentration of 100 mEq/L, a potassium concentration of 25 rnEq/L, and a pH of approximately 7.4 at room temperature. The primary containers used for the device are PVC free bags 1000ml, therefore they are free of phthalates. The solution may be used without any point of use filtration.
Servator M SALF is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

Type of device.
Sterile, non-pyrogen solution for perfusion/protection and preservation of organs.
NOT FOR INJECTION.

Package
Box containing 10 bags per carton of 1000 ml PVC free.

Model Number of Device: SERVM10DMA

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 M SALF Solution**	**PERF-GENQ® Pulsatile Perfusion Solution**	**NA**
Manufacturer	SALF spa, Italy	Waters Medical Syustems, LLC, Rochester, MN	NA
510(k) Number	K211842	K121736	NA
Classification & Product Code	876.5880; KDL	876.5880; KDL	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, Disposable	System, Perfusion, Kidney, Disposable	Same
Common Name	Cold Storage Solution	Cold Storage Solution	Same
Device Description	The Servator M SALF Solution is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explained kidneys. This solution has an approximate calculated osmolarity of 300	The PERF-GENO Pulsatile Perfusion Solution (PERF-GEN Solution) is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explained kidneys. This solution has an	Same

	mOsm/kg, a sodium concentration of 100 mEq/L, a potassium concentration of 25 rnEq/L, and a pH of approximately 7.4 at room temperature.	approximate calculated osmolarity of 300 mOsm/kg, a sodium concentration of 100 mEq/L, a potassium concentration of 25 rnEq/L, and a pH of approximately 7.4 at room temperature.	
Indication for Use	Servator M SALF Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.	The PERF-GENQ® Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and 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
Meets UNOS Policy	Yes	Yes	Same
pH	6.90-7.50 at 20°C	6.90-7.50 at 20°C	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	Particle Counts less than limits for Large Volume Injections per USP <788>; Biocompatible per ISO	Same

	10993-1 battery of tests for Externally Communicating Blood Path Indirect Contact for prolonged periods >24 hours.	10993-1 battery of tests for Externally Communicating Blood Path Indirect Contact for prolonged periods >24 hours.	
Device Standards of Conformity	ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 14971 ISO 15223-1 ISO 17665-1 USP 39 <71> USP 39 <85>	ISO 10993 Series Exact test series of predicate device are unknown	Subject device passed according to ISO Standards
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 method	Steam	Steam	Same
Nominal value	1000 mL bags	1000 mL bags	Same
Shelf Life	24 months	24 months	Same
Storage Temperature	Indoors with temperature at 2°- 25°C, without freezing.	Indoors with temperature at 2° - 25°C, without freezing.	Same
Interaction with other medical technology	Check the expiration date stated on the container. The expiration date refers to the product in unopened packaging. CAUTION: do not use the device after the expiry date stated on the container. Even though within its	Check the expiration date stated on the container. The expiration date refers to the product in unopened packaging. CAUTION: do not use the device after the expiry date stated on the container. Even though within its shelf	Same

	shelf life (device not expired), the solution must not be used, if the container is damaged or if there are visible particles, precipitates or contaminations.	life (device not expired), the solution must not be used, if the container is damaged or if there are visible particles, precipitates or contaminations.	

Solution qualitative and quantitative composition / Same for both Subject and Predicate

CONSTITUENT	Amount 1000 ml	Concentration (mM)
Adenine (free base)	0.68 g	5
Calcium Chloride (dihydrate)	0.068 g	0.5
Dextrose (+)	1.80 g	10
Glutathione (reduced)	0.92 g	3
HEPES (free acid)	2.38 g	10
Hydroxyethyl Starch	50.0 g	N/A
Magnesium Gluconate (anhydrous)	1.13 g	5
Mannitol	5.4 g	30
Potassium Phosphate (monobasic)	3.4 g	25
Ribose, D(-)	0.75 g	5
Sodium Gluconate	17.45 g	80
Sodium Hydroxide	0.70 g	N/A
Sterile Water for injection	to 1000 ml Volume	N/A

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 M SALF Solution has 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 is 24 months and the predicate device is 12 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 M 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 M SALF Solution** warrants a finding of substantial equivalence to the legally marketed PERF-GENQ® Pulsatile Perfusion Solution, and therefore, should have clearance for premarket activities in the United States.