August 14, 2019

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

Re: K190063  
Trade/Device Name: Servator C SALF Solution  
Regulation Number: 21 CFR 876.5880  
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories  
Regulatory Class: Class II  
Product Code: MSB  
Dated: July 10, 2019  
Received: July 15, 2019

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
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.


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,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastro-Renal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

Servator C SALF Solution is intended for flushing and cold storage of hearts 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.

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510(k) Summary – K190063

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: January 9, 2019

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/Model Names: Servator C SALF Solution
Submitter: SALF, S.p.A., Italy
Common Name: Organ perfusion and preservation solution
Classification Name: System and Accessories, Isolated Heart, Transport and Preservation
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulation Number: 21 CFR 876.5880
Product Code: MSB
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: K991594
Date Cleared July 30, 1999
Submitter: SangStat Medical Corporation, Fremont, CA
Trade Name: Celsior Cold Flush, Storage and Transport Solution for Hearts
Common Name: Organ perfusion and preservation solution
Classification Name: System and Accessories, Isolated Heart, Transport and Preservation
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulation Number: 21 CFR 876.5880
Product Code: MSB
Regulatory Class: II
Medical Specialty: Gastroenterology/Urology Panel

**Indications for Use**

**Servator C SALF Solution** is intended for flushing and cold storage of hearts at the time of their 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 C SALF Solution** is a clear to light yellow, single use only, sterile (by steam sterilization) and non-pyrogenic for hypothermic cardiac flushing and storage in preparation for transportation and eventual transplantation of the heart into the recipient.

The solution is slightly alkaline (pH 7.3 ± 0.2 at 20°C), slightly hypertonic (approximate calculated osmolarity 242-368 mOsmol/L) with low viscosity (1.15 cSt), and has a high buffering capacity (acidic approximately 11 mmol, alkaline approximately 7 mmol). After removal from refrigerated storage (2°-8°C or 36°-46°F), the cold solution is used to flush the heart immediately before removal from the donor and/or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation.

The primary containers used for the device are PVC free bags in 1000ml, therefore they are free of phthalates. The containers are in accordance with the reference European Pharmacopoeia and USP Pharmacopeia.

**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

<table>
<thead>
<tr>
<th>Device</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Servator C SALF Solution</td>
<td>Celsior Solution Cold Flush Storage and Transport Solution</td>
<td>NA</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>SALF spa, Italy</td>
<td>SangStat Medical Corp., USA</td>
<td>NA</td>
</tr>
<tr>
<td>Classification &amp; Product Code</td>
<td>876.5880; MSB</td>
<td>876.5880; MSB</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation Name</td>
<td>Isolated Kidney Perfusion and Transport System and Accessories</td>
<td>Isolated Kidney Perfusion and Transport System and Accessories</td>
<td>Same</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>System and Accessories, Isolated Heart, Transport and Preservation</td>
<td>System and Accessories, Isolated Heart, Transport and Preservation</td>
<td>Same</td>
</tr>
<tr>
<td>Common Name</td>
<td>Cold Storage Solution</td>
<td>Cold Storage Solution</td>
<td>Same</td>
</tr>
<tr>
<td>Device Description</td>
<td>Servator C is a clear to slightly yellow, sterile, non-pyrogenic, extracellular solution for hypothermic flushing and storage of hearts. The solution is slightly alkaline (pH 7.3 ± 0.2 at 20°C), slightly hypertonic (approximate calculated osmolarity 242-368 mOsmol/L) with low viscosity (1.15 cSt), and has a high buffering capacity (acidic approximately 11 mmol,</td>
<td>Celsior is a clear to slightly yellow, sterile, non-pyrogenic, extracellular solution for hypothermic flushing and storage of hearts. The solution is slightly alkaline (pH 7.3 ± 0.2 at 20°C), slightly hypertonic (approximate calculated osmolarity 242-368 mOsmol/L) with low viscosity (1.15 cSt), and has a high buffering capacity (acidic approximately 11 mmol,</td>
<td>Same</td>
</tr>
<tr>
<td>Indication for Use</td>
<td>Servator C SALF is intended for flushing and cold storage of hearts at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.</td>
<td>Celsior is intended for flushing and cold storage of hearts at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.</td>
<td>Same</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Organ storage and preservation for transplantation</td>
<td>Organ storage and preservation for transplantation</td>
<td>Same</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>System and Accessories, Isolated Heart, Transport and Preservation</td>
<td>System and Accessories, Isolated Heart, Transport and Preservation</td>
<td>Same</td>
</tr>
<tr>
<td>----------------------------</td>
<td>------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Mode of operation</td>
<td>Cold storage</td>
<td>Cold storage</td>
<td>Same</td>
</tr>
<tr>
<td>Container/Bag</td>
<td>PVC free bags</td>
<td>PVC free bags</td>
<td>Same</td>
</tr>
<tr>
<td>Solution qualitative and quantitative composition of 1000 ml of solution</td>
<td>Servator C is used for hypothermic cardiac flushing and storage in preparation for transportation and eventual transplantation of the heart into the recipient. The quantitative compositions of Servator C is: Mannitol 60 mmol Lactobionic Acid 80mmol Glutamic Acid 20mmol Histidine 30mmol Calcium Chloride 0.25 mmol Potassium Chloride 15mmol Magnesium Chloride 13mmol Sodium Hydroxide 100mmol Reduced Glutathione 3mmol Water for Injection, Up to 1 Liter</td>
<td>Celsior is used for hypothermic cardiac flushing and storage in preparation for transportation and eventual transplantation of the heart into the recipient. The quantitative compositions of Celsior is: Mannitol 60 mmol Lactobionic Acid 80mmol Glutamic Acid 20mmol Histidine 30mmol Calcium Chloride 0.25 mmol Potassium Chloride 15mmol Magnesium Chloride 13mmol Sodium Hydroxide 100mmol Reduced Glutathione 3mmol Water for Injection, Up to 1 Liter</td>
<td>Same</td>
</tr>
<tr>
<td>pH</td>
<td>pH 7.3 ± 0.2 at 20°C</td>
<td>pH 7.3 ± 0.2 at 20°C</td>
<td>Same</td>
</tr>
<tr>
<td>Osmolality</td>
<td>242-368 mOsm/K</td>
<td>242-368 mOsm/K</td>
<td>Same</td>
</tr>
<tr>
<td>Bag material</td>
<td>PVC free material</td>
<td>PVC free material</td>
<td>Same</td>
</tr>
<tr>
<td>Particulate Matter and Biocompatibility</td>
<td>Particle Counts less than limits for Large Volume Injections per USP &lt;788&gt;; Biocompatible per ISO 10993-1 battery of tests for Externally</td>
<td>Particle Counts less than limits for Large Volume Injections per USP &lt;788&gt;; Biocompatible per ISO 10993-1 battery of tests for Externally</td>
<td>Same</td>
</tr>
</tbody>
</table>
| Device Standards of Conformity | Communicating Blood Path Indirect Contact for prolonged periods >24 hours. | Communicating Blood Path Indirect Contact for prolonged periods >24 hours. | ISO 10993-1  
ISO 10993-2  
ISO 10993-4  
ISO 10993-5  
ISO 10993-10  
ISO 10993-11  
ISO 11607-1  
ISO 11607-2  
ISO 11737-1  
ISO 14971  
ISO 15223-1  
ISO 17025  
ISO 17665-1  
USP 39 <71>  
USP 39 <85>  
USP 41 <151>  
ISO 17665 Series  
USP <788>  
USP <1211>  
Exact test series of predicate device are unknown  
Subject device passed according to ISO Standards |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protecting Overwrap bag</td>
<td>Yes and contains an oxygen absorber</td>
<td>Yes and contains an oxygen absorber</td>
</tr>
<tr>
<td>Bag connections</td>
<td>1 flip off, 1 needle point</td>
<td>1 flip off, 1 needle point</td>
</tr>
<tr>
<td>Single use only</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>Steam</td>
<td>Bag is sterilized by ethylene oxide and solution is aseptically processed.</td>
</tr>
<tr>
<td>Nominal value</td>
<td>1000 mL bags</td>
<td>1000 mL bags</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>24 months</td>
<td>24 months</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>Refrigerated Storage between 2°C to 8°C, without freezing (36° – 46° F)</td>
<td>Indoor controlled between 2°C to 8°C, without freezing (36° – 46° F)</td>
</tr>
</tbody>
</table>
NOTE. . . The composition list is identical to the subject 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 minor differences do not make the subject device any less safe and effective as the predicate device.

The Servator C SALF Solution is the same in 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. The subject and predicate device have a different method of sterilization; however, both devices are provided sterile and have been validated per ISO standards. 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 C 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 C SALF Solution warrants a finding of substantial equivalence to the legally marketed Celsior™ Cold Storage Solution, and therefore, should have clearance for premarket activities in the United States.