October 20, 2017

S.A.L.F. S.p.A.
% Joyce St. Germain
Regulatory Department Manager
510k FDA Consulting
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Ormond Beach, Florida 32176

Re: K170150
Trade/Device Name: Servator H SALF Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion and Transport System and Accessories
Regulatory Class: Class II
Product Code: KDL, MSB
Dated: September 7, 2017
Received: September 19, 2017

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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)*
K170150

Device Name
Servator H SALF Solution

Indications for Use *(Describe)*
The Servator H SALF solution is indicated for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the 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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510k FDA Consulting
Medical Device Clearance

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510(k) Summary - K170150

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Device Classification

Trade/Model Names:	Servator H SALF Solution
Common Name:	Organ perfusion and preservation solution
Classification Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Product Code:	KDL, MSB
Regulatory Class:	2
Medical Specialty:	Gastroenterology/Urology Panel

Predicate Device

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

510(k) Number:	K043461
Date Cleared	February 28, 2005
Trade Name:	Custodiol HTK
Common Name:	Organ perfusion and preservation solution
Classification Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Product Code:	KDL, MSB
Regulatory Class:	2
Medical Specialty:	Gastroenterology/Urology Panel

Indications for Use

The Servator H SALF solution is indicated for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.

Intended Use

The **Servator H SALF Solution** is intended for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or immediately after removal from the donor. The solution is for single use, is sterile (by steam sterilization) and non-pyrogenic.

Device Description

The **Servator H SALF** solution is intended for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal form the donor or immediately after removal from the donor. The solutions is left in the organ vasculature during hypotermic storage and transportation (not for continuous perfusion) to the recipient. **Servator H SALF** solution is based on the principle of inactivating organ function by withdrawal of extracellular sodium and calcium, together with intensive duffering of the extrcellular space by means of histidine/histidine HCI, so as to prolong the period for which organs will tolerate interruption of blood and oxygen supply. Only a small portion of the osmolality of the **Servator H SALF** solution is due to the sodium and potassium. The composition of the **Servator H SAL**F is similar to that of extracellular fluid. All of the components of the **Servator H SALF** solution occur naturally in the body.

The **Servator H SALF** solution is relatively low in postassium concentrations so that residual solution in the transplanted organ poses no danger to the recipient. This is particularyly important in organs that take up relatively large amounts of the perfusate, which may find its way into the recipient's circulation.

Comparison of Technological Characteristics with Predicate

The indications for use of the subject and predicate devices are identical and the technologies are substantially equivalent.

The following table compares technological and other characteristics of the subject and predicate device.

Table of Comparison

Table 12.1 -- Technological Comparison

	Subject Device	Predicate Device	Comparison
Device	**Servator H SALF**	**Custodiol HTK**	**NA**
510k Number	**K170150**	**K043461**	
Manufacturer	S.A.L.F. S.p.A. (Italy)	Dr. Franz Kohler Chemi GmbH (Germany)	NA
Classification & Product Code	876.5880; KDL, MSB	876.5880; KDL,MSB	Same
Classification Name	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories	Same
Device Description	Set, Perfusion, Kidney, Disposable	Set, Perfusion, Kidney, Disposable	Same
Common Name	Organ perfusion and preservation solution	Organ perfusion and preservation solution	Same
Indications for Use	The Servator H SALF solution is indicated for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal	The Custodiol HTK solution is indicated for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or	Same

	from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.	immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.	
Intended for Use	The **Servator H SALF Solution** is intended for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or immediately after removal from the donor. The solution is for single use, is sterile (by steam sterilization) and non-pyrogenic.	The **Custodiol HTK Solution** is intended for perfusion and flushing donor kidneys, liver, pancreas, and heart prior to removal from the donor or immediately after removal from the donor.	Same
Meets UNOS Policy	YES	YES	Same
Container/Bag	PVC free bags	PVC free bags	Equivalent
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, heart and pancreas	Used for kidneys, liver, heart and pancreas	Same

Product State	Liquid - Solution	Liquid - Solution	Same
Model Numbers	Servator H SALF, 1000ml / SERVH10DMA Servator H SALF, 2000ml / SERVH20DM	Bag, 1000 ml / 25767-735-45 Bag, 2000ml / 25767-735-49 Bag, 5000ml / 25767-735-46	**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, 2000 ml and 5000 ml.	**Equivalent Predicate device different packaging available**
Sterilization Method	Steam	Steam	Same
Physical Properties	pH: 7.02 – 7.20 at 25° C; 7.40 – 7.45 at 4° C Osmolality: 310 mOsm/Kg	pH: 7.02 – 7.20 at 25° C; 7.40 – 7.45 at 4° C Osmolality: 310 mOsm/Kg	Same
Manufacture Standards of Conformity	ISO 9001:2008 ISO 13485:2003 GMP Certification	Unknown	Subject meets current standards
Shelf Life	12 Months	12 Months	Same
Device Standards of Conformity	Subject device passed according to ISO standards	Unknown	Subject device passed according to ISO standards

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 predicate has additional sizes of bags and a bottle package.

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 testing was required for this device. The Cytotoxicity, Irritation, System Toxicity and Haemocompatibility tests were all performed. The subject device passed all biocompatibility test standards.

Sterilization and Shelf Life testing and evaluation was required for the subject device. The Validation of Sterility, Validation Method LAL Turbidimetric and Stability were all performed and the results passed the device on all test standards performed. Steam sterilization and storage conditions are the same. Shelf life for the subject and predicate device are 12 months.

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

Performance Testing including but not limited to chemical analysis was completed as a direct comparison between the subject and predicate device. The subject device proved to be substantially equivalent to the predicate. The comparison chart is shown in this summary and performance reports are included in the submission.

Conclusion

The subject and predicate devices have the same intended use and are substantially equivalent in technological characteristics and performance (since they have, in fact, the same composition). The Servator H SALF does not raise any questions regarding new questions of 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 H SALF warrants a finding of substantial equivalence to the legally marketed original Custodiol HTK Solution, and therefore, should have clearance for premarket activities in the United States.