



Food and Drug Administration
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September 18, 2015

Preservation Solutions, Inc.
% Neil Burris
Principal Consultant
Neil Burris and Associates
4250 Grove Street
Denver, CO 80211

Re: K151728
Trade/Device Name: CoStorSol® plus G
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories.
Regulatory Class: II
Product Code: KDN
Dated: June 24, 2015
Received: June 26, 2015

Dear Neil Burris,

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 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" (21CFR 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 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 yours,

Herbert P. Lerner -
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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

Indications for Use

510(k) Number (if known)

K151728

Device Name

CoStorSol plus G

Indications for Use (Describe)

CoStorSol® plus G is intended for the flushing and cold storage of liver, kidney, 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.

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510(k) SUMMARY

SUBMITTER INFORMATION

- A. Company Name: Preservation Solutions Inc.
- B. Company Address: 1099 Proctor Drive
Elkhorn, Wisconsin 53121
- C. Company Phone: 262 723 6715
- D. Company Facsimile: 262 723 4013
- E. Contact Person: William Wagner
Quality Assurance Director

DEVICE IDENTIFICATION

- A. Device Trade Name: CoStorSol® *plus G*
- B. Device Common Name: Organ Storage Solution
- C. Classification Name: Isolated kidney perfusion and transport system and accessories
- D. Class II (21 CFR 876.5880)
- E. Device Code: KDN

IDENTIFICATION OF PREDICATE DEVICES

CoStorSol® cold storage solution cleared to market under:

Premarket Notifications K091245, K083453, and K073693.

is an exact predicate to the proposed device CoStorSol® *plus G*.

DEVICE DESCRIPTION

Preservation Solutions, Inc. manufactures CoStorSol® *plus G* according to a “recipe” pioneered at the University of Wisconsin by Folkert O. Belzer, MD and James H. Southard, PhD. Indeed, this cold storage solution is often referred to as “Belzer UW” solution. The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and phosphoric compounds.

CoStorSol® *plus G* is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution is packaged in 1-liter bags, to which 0.922 g of

sterile glutathione may be added just prior to use. The solution must be chilled to between 2° and 6° C prior to use.

INDICATIONS FOR USE

INTENDED USE

CoStorSol® *plus G* is intended for the flushing and cold storage of liver, kidney, and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

COMPARISON TO PREDICATE DEVICES

CoStorSol® solution received substantial equivalence determinations after submissions filed under premarket notification (510(k)) numbers K091245, K083453, and K073693. The modified device, CoStorSol® *plus G*, is exactly the same as the predicate device, except that the new device will include a single vial of sterile glutathione powder (0.922 g). The glutathione is included as a convenience should the attending physicians, and/or transplant team, choose to use it as an optional additive to 1 Liter of CoStorSol® at the time of use. The Instructions for Use of CoStorSol® have always included statements advising the optional addition of 0.922 g of glutathione when deemed necessary due to the exact circumstances of the transplant case. Including a vial of glutathione in a package of CoStorSol® *plus G* thus represents no change to either the intended use or the specific methods of use for the device.

Substantial Equivalence Comparison Table for CoStorSol® *plus G* vs. CoStorSol®

| Device Attribute | CoStorSol® <i>plus G</i> (Proposed Device) | CoStorSol® K091245 (Predicate Device) | Equivalent? |
|---------------------|---|---|-------------|
| Intended Use | •CoStorSol® <i>plus G</i> is intended for the flushing and cold storage of liver, kidney, 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. | Identical |
| Preparation for Use | Chill to 2° to 6° C without freezing; <i>Required addition to 1L of CoStorSol®:</i> Penicillin G-200,000 units, Insulin-40 Units, Dexamethasone-16mg; <i>Optional addition to 1L CoStorSol®:</i> glutathione 0.922g | Chill to 2° to 6° C without freezing; <i>Required addition to 1L of CoStorSol®:</i> Penicillin G-200,000 units, Insulin-40 Units, Dexamethasone-16mg; <i>Optional addition to 1L CoStorSol®:</i> glutathione 0.922g | Identical |

Continued next page

| Device Attribute | CoStorSol® <i>plus G</i> (Proposed Device) | CoStorSol® K091245 (Predicate Device) | Equivalent? |
|---|---|---|---|
| Chemical Composition | A synthetic medium of defined organic, and inorganic, soluble chemical compounds with specified purity. pH = 7.4 nominal osmolality \cong 320 mOsM | A synthetic medium of defined organic, and inorganic, soluble chemical compounds with specified purity. pH = 7.4 nominal osmolality \cong 320 mOsM | Identical |
| Packaging - How Supplied | Filter sterilized using 0.1 μ membrane(s) and aseptically filled into biocompatible, 1 liter flexible solution bags made of laminated plastic with an ethylene-vinyl-acetate (EVA) layer contacting the solution. The bags have integrated delivery set ports, and are packaged with a single 10mL polyethylene terephthalate (PETG) vial holding 0.922 g sterile non-pyrogenic glutathione. CoStorSol® is non-pyrogenic. Shelf packs contain 6, 1-liter bags and 6 vials of glutathione powder | Filter sterilized using 0.1 μ membrane(s) and aseptically filled into biocompatible, 1 liter flexible solution bags made of laminated plastic with an ethylene-vinyl-acetate (EVA) layer contacting the solution. The bags have integrated delivery set ports. CoStorSol® is non-pyrogenic. Shelf packs contain 10, 1-liter bags. | Substantially Equivalent – Sterile glutathione, an optional additive to both the subject device and predicate, is provided with 1L units of CoStorSol®. |
| Sterility | Sterility Assured via 0.1 μ membrane filtration | Sterility Assured via 0.1 μ membrane filtration | Identical |
| Storage Temperature and Shelf Life | Indoors with temperature controlled at 2°-25°C, without freezing; 1year (12 month) shelf life | Indoors with temperature controlled at 2°-25°C, without freezing; 1 year (12 month) shelf life | Identical |
| Actions and Functions | Use cold solution to flush organ immediately before and/or after removal to clear blood from the vasculature. Store organs cold in aliquot of the same solution to maintain histological viability by depressing metabolism. | Use cold solution to flush organ immediately before and/or after removal to clear blood from the vasculature. Store organs cold in aliquot of the same solution to maintain histological viability by depressing metabolism. | Identical |
| 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. | Identical |
| Interaction with Other Medical Technology | CoStorSol® <i>plus G</i> is not intended for continuous perfusion. Standard transplantation surgical expertise and techniques are required. | CoStorSol® is not intended for continuous perfusion. Standard transplantation surgical expertise and techniques are required. | Identical |

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Test results have shown CoStorSol® *plus G* to be a biocompatible solution, supplied in flexible solution bags made of laminated plastic with an ethylene-vinyl-acetate (EVA) layer contacting the solution, which have likewise been tested and shown to be biocompatible. The ISO 10993 series of standards were referenced during the planning and execution of all biocompatibility testing,

including: cytotoxicity, acute systemic toxicity, dermal sensitization, hemolysis, and intracutaneous reactivity/irritation. Particulate matter does not exceed the limits set in USP Section <788>, for large volume injections.

The 1 Liter of CoStorSol®, and the single vial of glutathione, are both supplied sterile and non-pyrogenic in order to assure safety for transplant recipients.

Sterilization processes for CoStorSol® *plus G* were validated according to the ISO 13408 series applicable to aseptic filling, or the ISO 11137 series of standards application to radiation sterilization, as appropriate.

Preservation Solutions, Inc. has validated shelf life for CoStorSol® *plus G* using a combination of accelerated aging and natural aging protocols, supporting expiry periods of up to 1 year. Shelf life verification tests show that aged CoStorSol® *plus G* remains functionally equivalent to newly manufactured solution via tests for biocompatibility, particulate matter, chemical identity, general appearance, weight loss, and package integrity.

CONCLUSION

The above statements establish substantial equivalence between the predicate CoStorSol® product, and CoStorSol® *plus G*.