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510(k) SUMMARY

SUBMITTER INFORMATION

JUL - 3 2008

A. Company Name: Preservation Solutions Inc.

B. Company Address: 980 Proctor Drive
Elkhorn, Wisconsin 32121

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®

B. Device Common Name: Organ Storage Solution

C. Classification Name: Organ Storage Solution systems and accessories

D. Class II (21 CRF 876.5880)

E. Device Code: KDL

IDENTIFICATION OF PREDICATE DEVICES

CoStorSol® is a cold storage solution for harvested organs, which is substantially equivalent to a ViaSpan® solution (K944866).

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DEVICE DESCRIPTION

Preservation Solutions, Inc. manufacturers CoStorSol® according to a "recipe" pioneered at the University of Wisconsin by Dr. Folkert O. Belzer. The cold storage solution is still referred to as "Belzer UW" solution, even though it has been marketed under the trade name ViaSpan®. The formulation includes soluble colloids, buffers, sodium and postassium salts, redox stabilizers, and phosphoric compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

CoStorSol® 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.

INDICATIONS FOR USE

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.

COMPARISON TO PREDICATE DEVICES

ViaSpan® (Belzer – UW) Organ Solution, cleared under 510(k) K944866 serves as an exact predicate for Preservation Solutions, Inc.'s CoStorSol®, in that it is an identical solution with exactly the same intended use and chemical composition. CoStorSol® and the predicate solution, Viaspan®, are both supplied in 1-liter flexible bags to ease connection to standard administration sets for flushing of harvested organs. The two solutions are designed for refrigerated storage without freezing, and for use cold. Both are used as a vasculature flush medium for an organ then as a cold storage medium.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Test results have shown CoStorSol® itself to be a biocompatible solution, supplied in flexible solution administration pouches, 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. CoStorSol® is supplied sterile and non-pyrogenic in order to assure safety for transplant recipients. Sterilization processes were validated according to either ISO 17665 or USP Section <1116>, as appropriate.

Chemical analyses on both fresh and aged samples of CoStorSol® show it to be identical to the predicate solution. Furthermore, Fourier transformed infrared scans confirmed stability and chemical identity for the CoStorSol® product.

CONCLUSION

The above statements establish substantial equivalence between CoStorSol® and the cited predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2008

Preservation Solutions, Incorporated
% Mr. Neil Burris
Neil Burris and Associates
4250 Grove Street
DENVER CO 80211

Re: K073693
Trade/Device Name: CoStorSol®
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: June 13, 2008
Received: June 17, 2008

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K073693

4. Statement of Indication for Use

Device Name: CoStorSol®

Indications for Use

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.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073693