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510(k) SUMMARY

JAN 21 2009

SUBMITTER INFORMATION

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 Isolated kidney perfusion and transport system and accessories

D Class II (21 CRF 876 5880)

E Device Code KDN

IDENTIFICATION OF PREDICATE DEVICES

CoStorSol®, to be stored at ambient room temperature, is a transplant graft storage solution for harvested organs, which is substantially equivalent to the original CoStorSol® solution cleared to market under 510(k) K073693

DEVICE DESCRIPTION

Preservation Solutions, Inc manufacturers CoStorSol® according to a "recipe" pioneered at the University of Wisconsin by Dr Folkert O Belzer Indeed, the 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 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

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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

CoStorSol®, cleared under 510(k) K073693 with a specified shelf life of one (1) year at 2°C to 6°C, serves as an exact predicate for Preservation Solutions, Inc 's CoStorSol® with the same one (1) year shelf life when stored at ambient room temperatures up to 25°C There has been no change in the formulation, packaging, or intended use for the product The proposed CoStorSol® solution is identical to the predicate Again, only the long-term storage temperature range has changed The solution was, and is still designed for storage without freezing CoStorSol® will continue to be supplied in 1-liter flexible bags to ease connection to standard administration sets for flushing of harvested organs CoStorSol® transplant solution, if stored at room temperature, must be chilled prior to use CoStorSol® is used as an initial vasculature flush medium for an organ, and 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 <1211>, as appropriate

Chemical analyses on both fresh reference samples, and samples naturally aged at 25° ± 2°C, show CoStorSol® to be identical to the predicate solution

CONCLUSION

The above statements establish substantial equivalence between CoStorSol® stored for up to one year at room temperature, and predicate solution stored under refrigeration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Preservation Solutions, Inc
c/o Mr Neil Burns
Principal, Neil Burns & Associates
4250 Grove Street
DENVER CO 80211

JAN 21 2009

Re K083453
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 November 18, 2008
Received November 21, 2008

Dear Mr Burns

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 os 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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 suppot/index html

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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5 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 K083453