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510(k) SUMMARY

Organ Recovery Systems, Inc.
KPS-I™ The Kidney Perfusion Solution

1. SUBMITTER INFORMATION

A. Organ Recovery Systems, Inc.,
701 E. Bay St., Suite 433
MSC 1119 Port City Center
Charleston, SC 29403

Federal Identification Number: 36-4256620

B. Official Correspondent:

Stanley J. Harris,
Director, Regulatory and Clinical Affairs

Phone: (843) 853-6756 ex. 29
Fax: (843) 722-6657

2. DEVICE IDENTIFICATION

A. Classification Name:	Isolated kidney perfusion and transport system and accessories (21 CFR 876.5880)
B. Classification:	Class II, Gastroenterology/Urology Panel
C. Common/Usual Name:	Cold Storage Solution
D. Proprietary Name:	KPS-I™, The Kidney Perfusion Solution

3. PREDICATE DEVICE

Belzer MPS™ (UW Kidney Preservation Solution), Trans-Med Corporation (Elk River, MN), 510(k) Notification Number K972066

Indications for Use: Belzer MPS™ is the UW-gluconate perfusion solution indicated for flushing and continuous hypothermic machine perfusion of explanted donor kidneys.

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Device Description: Belzer MPS™ is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. This solution has an approximate calculated osmolarity of 300mOsM, a sodium concentration of 100mEq/L, a potassium concentration of 25mEq/L, and a pH of approximately 7.4 at room temperature. Based upon the sodium/potassium ratio, the composition of Belzer MPS™ is thus consistent with that of an extracellular solution.

4. DESCRIPTION OF DEVICE

KPS-I™, The Kidney Perfusion Solution
(University of Wisconsin Machine Perfusion Solution Formulation)

Indications for Use: KPS-I™, The Kidney Perfusion Solution is intended to be used for in-vitro flushing and temporary continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor, in preparation for storage, transportation and eventual transplantation into a recipient.

Device Description: KPS-I™, The Kidney Perfusion Solution (UW Machine Perfusion Solution) is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. This solution has an approximate calculated osmolarity of 300mOsM, a sodium concentration of 100mEq/L, a potassium concentration of 25mEq/L, and a pH of approximately 7.4 at room temperature. Based upon the sodium/potassium ratio, the composition is thus consistent with that of an extracellular solution.

KPS-I™ should be cooled to about 5 °C (4 °C to 8 °C) prior to use and should be used in a perfusion machine that is capable of maintaining temperature within the above specified range.

It is recommended that the KPS-I™ be stored between 2 °C and 8 °C. The solution should not be frozen or exposed to excessive heat.

KPS-I™, The Kidney Perfusion Solution is suitable for a mean perfusion time of 29 hours +/- 8 hours.

5. SUBSTANTIAL EQUIVALENCE

A. **Indications for Use:** KPS-I™, The Kidney Perfusion Solution are identical in intended use to Belzer MPS™.

B. **Technological Characteristics:** KPS-I™, The Kidney Perfusion Solution and Belzer MPS™ are both clear, sterile, non-pyrogenic solutions containing various components in the categories of ions, pH buffers, impermeants, colloids and pharmacologics intended to reduce metabolism and preserve

physiological conditions of explanted organs during cold storage. They have the same pH value, 7.4 +/-.15 and an osmolarity of 300 +/-15mOsm/L. . The solutions are the same in that both the KPS-I™, The Kidney Perfusion Solution and Belzer MPS™ contains a sodium/potassium ratio (high/low) characteristic of an extracellular solution enables it to function well for hypothermic machine perfusion.

6. Conclusion

KPS-I™, The Kidney Perfusion Solution has the same intended use as Belzer MPS. The solution formulation is identical and packaging system that is employed is identical to the predicate device. Data contained in the 510(k) demonstrates that KPS-I™, The Kidney Perfusion Solution is substantially equivalent to Belzer MPS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Mr. Stan Harris
Director, Regulatory and Clinical Affairs
Organ Recovery Systems
Charleston Research Center
701 East Bay Street, Suite 433
MSC 1119, Port City Center
CHARLESTON SC 29403

Re: K013575
Trade/Device Name: KPS-I™, The Kidney Perfusion Solution
Regulation Number: 21 CFR §876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: 78 KDN
Dated: October 22, 2001
Received: October 29, 2001

Dear Mr. Harris:

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

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K013575

Device Name: KPS-I™ The Kidney Perfusion Solution

Indications For Use:

KPS-I™ The Kidney Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor, in preparation for storage, transportation and eventual transplantation into a recipient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013575

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)