

## 510(k) Summary

**Submitter:** Organ Recovery Systems, Inc.

**Contact Person:** PJ Pardo,  
Director, Regulatory, Clinical & Quality Affairs  
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**Date Prepared:** 04 Jun 2009

**Trade Name:** SPS-1™

**Common Name:** Static Preservation Solution

**Classification:** Class II  
System, Perfusion, Kidney  
Isolated kidney perfusion and transport system and accessories  
21 CFR §876.5880

**Product Code:** KDN

**Predicate Device(s):** The subject device is equivalent to the following devices:

- CoStorSol® K083453 and K073693
- ViaSpan® K944866

**Device Description:** SPS-1™ is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolality of 320 mOsm, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

**Intended Use:** SPS-1™ 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.

**Functional and Safety Testing:** To verify that device design met its functional and performance requirements, representative sample of the device underwent testing such as biocompatibility, sterility, chemical identification and particle enumeration testing in accordance with applicable industry standards and/or FDA guidance documents. The primary evidence for equivalence is that SPS-1™ Static Preservation Solution and the predicate device are manufactured by the same process, with exactly the same chemical composition and have the same intended use.

**Conclusion:** Organ Recovery Systems, Inc., considers the SPS-1™ Static Preservation Solution to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in that they are manufactured by the same process, with exactly the same chemical composition and have the same indications for use.

MAR 11 2010



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G6  
Silver Spring, MD 20993-0002

Mr. P. J. Pardo  
Director, Regulatory, Clinical & Quality Affairs  
Organ Recovery Systems, Inc.  
1 Pierce Place, Suite 475 W  
ITASKA IL 60143

MAR 11 2010

Re: K091656  
Trade/Device Name: SPS-1™ Static Preservation Solution  
Regulation Number: 21 CFR §876.5880  
Regulation Name: Isolated kidney perfusion and transport system and accessories  
Regulatory Class: II  
Product Code: KDL  
Dated: March 5, 2010  
Received: March 8, 2010

Dear Mr. Pardo:

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

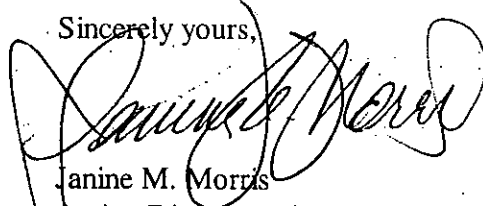
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



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

Enclosure

**Indications for Use Statement**

Device Name: SPS-1™ Static Preservation Solution

SPS-1™ 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.

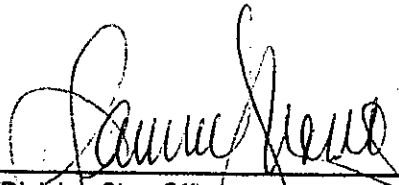
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 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   K091656