

## 510(k) SUMMARY

### SUBMITTER INFORMATION

AUG - 8 2008

- A. Company Name: Preservation Solutions Inc.
- B. Company Address: 980 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: MaPerSol®
- B. Device Common Name: Organ Preservation 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

MaPerSol® is a organ preservation solution for explanted kidneys, which is substantially equivalent to a both Belzer-MPS™, UW Machine Perfusion Solution (K972066) and KPS-1 Kidney Perfusion Solution (K022391).

### DEVICE DESCRIPTION

Preservation Solutions, Inc. manufacturers MaPerSol® according to a "recipe" pioneered at the University of Wisconsin by Dr. Folkert O. Belzer and Dr. James Southard. The kidney flushing and perfusion storage solution may still be referred to as Belzer-MPS™, UW Machine Perfusion Solution, and is currently sold under that trade name (Trans-Med Corporation, Elk River, MN), as well as under the trade name KPS-1 (Organ Recovery Systems, Des Plaines, IL). The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

MaPerSol® is a colorless, sterile, non-pyrogenic, non-toxic solution for in-vitro flushing and continuous perfusion of explanted kidneys. The solution is packaged in 1-liter bags. The Food and Drug Administration regulates such solutions as medical devices as referenced below.

## **INDICATIONS FOR USE**

MaPerSol® organ preservation solution is intended for in-vitro flushing and continuous hypothermic machine perfusion of explanted kidneys.

## **COMPARISON TO PREDICATE DEVICES**

MaPerSol® is identical in formulation to two (2) predicate products, KPS-1 Kidney Perfusion Solution (K022391) and Belzer-MPS™ UW Machine Perfusion Solution (K972066). The solutions maintain organ cleanliness and viability prior to transplantation.

## **BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING**

MaPerSol®, mixed and filled according to written procedures under routine conditions at the manufacturer's (Preservation Solutions, Inc.) site, has been verified as biocompatible and meets the particulate matter limits for large volume parenterals (LVP's).

Compounded and fully dissolved MaPerSol® is filter sterilized and aseptically filled into flexible solutions bags fitted with ports suitable for aseptic connection to standard infusion or administration sets. Sterilization processes have been validated following national and international standards and guidance documents.

A shelf life of 1 year was confirmed using chemical, microbiological, and toxicological tests, as well as via Fourier transformed infrared spectrometry. MaPerSol® solution, fully packaged and labeled as if for sale and stored for approximately 12 months, compares favorably with fresh MaPerSol®. No deleterious effects due to aging occur in either the solution or its flexible pouch container.

Routine chemical tests for osmolarity/osmolality and pH show consistent equivalence among the proposed device MaPerSol® and the two (2) predicates.

## **CONCLUSION**

The above statements establish substantial equivalence between MaPerSol® and the cited predicates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 8 2008

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

Re: K080432  
Trade/Device Name: **MaPerSol®**  
Regulation Number: 21 CFR §876.5880  
Regulation Name: Isolated kidney perfusion and transport system and accessories  
Regulatory Class: II  
Product Code: KDN  
Dated: July 16, 2008  
Received: July 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" (21 CFR 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  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

4. Statement of Indication for Use

Device Name: MaPerSol®

Indication for Use

MaPerSol® organ preservation solution is intended for in-vitro flushing and continuous hypothermic machine perfusion of explanted kidneys.

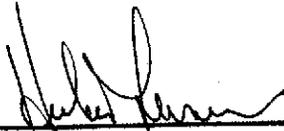
Prescription Use **XXXX**  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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 K080432