MAY 2 3 2014

510(k) Summary
Paragonix Sherpa Pak Kidney Transport System

Submitter:	Paragonix Technologies, Inc. c/o Vaughn & Associates 639 Granite Street Braintree, MA02184
Contact Person:	Leo Basta NorthStar Biomedical Associates 93 Benefit Street Providence, RI, 02904 Phone: 617.834.9866 lbasta@northstarbiomedical.com
Date Prepared:	December 23, 2013
Trade Name:	Paragonix Sherpa Pak Kidney Transport System
Classification Name:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Product Code:	KDN
Predicate Devices:	Sherpa Pak Cardiac Transport System, 21 CFR 876.5880 – Paragonix Technologies, Inc., K123326, Product Code MSB Avid Medical Custom Procedure Tray, 21 CFR 878.4800 – Avid Medical, Class I exempt, Product Code KDD CoStorSol, 21 CFR 876.5880. Preservation Solutions Inc. – K091245, Product Code KDN
Device Description:	The Paragonix Sherpa Pak Kidney Transport System is a device intended to provide a safe, consistent method for cold ischemic storage and transport of donor kidney organs to recipients for transplantation. The Sherpa Pak Kidney Transport System consists of 1) an outer shipper which contains various non-ice based temperature controlled packaging elements, 2) an inner and outer hard shell container (i.e. Sherpa Pak/Sherpa Pak Shell) which provides a double,

rigid barrier container in which the donor kidney is immersed and suspended in a Cold Storage Fluid cleared for use in storing and transporting donor organs and 3) a temperature display and timer to monitor temperature and elapsed time of transport, respectively. The device is identical to the cleared Sherpa Pak Cardiac Transport System with the exception of the indications for use specific to donor organs, and removal of a connector in the canister component.

Intended Use: Organ storage and preservation for transplantation.

Indications for Use: The Sherpa Pak Kidney Transport System is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ.

The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.

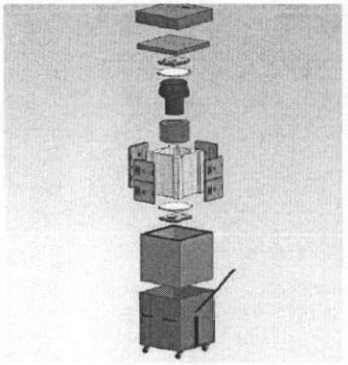
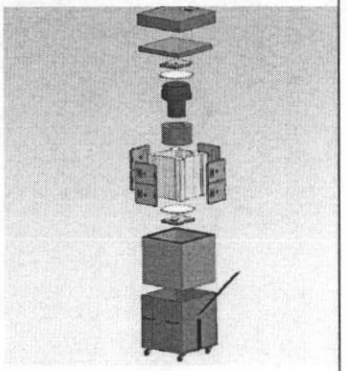
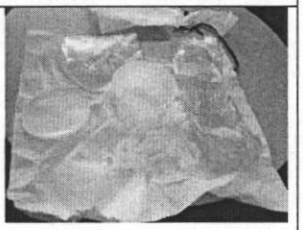
Functional Testing: Descriptive information and laboratory bench testing were provided to demonstrate the device meets its design specifications, performs as intended, and is safe for its intended use. Additional biocompatibility testing was not necessary as there were no material changes from the device cleared under K123326.

Specifically, testing to demonstrate that the Sherpa Pak Kidney Transport System provides a transport system robust enough to protect the donor organ during transport and maintain temperature throughout the duration of transport, was included. Thermal qualification testing demonstrated the ability of the Sherpa Pak Kidney Transport System to maintain the required temperature through 24 hours.

Device Characteristic Comparison

Characteristic	Proposed Sherpa Pak Kidney Transport System [current 510(k)]	Proposed Sherpa Pak Cardiac Transport System Device – K123326	CoStorSol Cold Storage Solution – K091245	Avid Medical Custom Procedure Tray – Class I 510(k) Exempt
Intended Use	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation
Indications for Use	"The Sherpa Pak Kidney Transport System is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ. The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours."	"The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts, up to 4 hours, during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart."	"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."	Specific indication statement is unknown. However, the Avid procedure tray is sold to organ procurement centers, for organ packaging with Cold Storage Solutions for transportation to recipient for transplantation.
Regulation Number	878.5880	878.5880	878.5880	878.4800
Product Code	KDN	MSB	KDN	KDD
Device Classification Name	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Kit, surgical instrument, disposable.
Mode of Operation	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage
Meets UNOS Policy 5[1]	Yes	Yes	Yes	Yes

[1] http://www.optn.transplant.hrsa.gov

Characteristic	Proposed Sherpa Pak Kidney Transport System [current 510(k)]	Proposed Sherpa Pak Cardiac Transport System Device – K123326	CoStorSol Cold Storage Solution – K091245	Avid Medical Custom Procedure Tray – Class I 510(k) Exempt
Organ container	Two rigid airtight containers one of which contains the cold storage solution in which the organ is immersed.	Two rigid airtight containers one of which contains the cold storage solution in which the heart is immersed.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Kidney Transport System or the Avid custom procedure tray tub.	Plastic tub with lid and bags.
Cooling	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels	Temperature preconditioned. Relies on transport system for type of cooling and maintenance of temperature	Temperature preconditioned storage solution, ice and water. Requires use of a commercial cooler (e.g., igloo style).
System components	 • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell ***without connector*** • Temperature data logger • Timer	 • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell ***with heart connector*** • Temperature data logger • Timer	 • Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).	 • 64 oz. tub with lid • Polyethylene bags • Procedure wrap • Twill tape Once heart is packaged, kit is stored on ice in a standard cooler.

Characteristic	Proposed Sherpa Pak Kidney Transport System [current 510(k)]	Proposed Sherpa Pak Cardiac Transport System Device – K123326	CoStorSol Cold Storage Solution – K091245	Avid Medical Custom Procedure Tray – Class I 510(k) Exempt
Single Use/Reuse	Entire system is single use/patient only.	Entire system is single use/patient only.	Single use/patient only.	Single use/patient only. Commercial cooler may be reused.
Sterilization	Sherpa Pak and Sherpa Pak Shell are sterilized by gamma irradiation. All other components are non-sterile.	Sherpa Pak, Sherpa Pak Shell, and Heart connector are sterilized by gamma irradiation. All other components are non-sterile.	Sterilized.	EO sterilized.
Biocompatibility	Direct and indirect organ contact materials have been tested for biocompatibility.	Direct and indirect heart contact materials have been tested for biocompatibility.	Yes.	Unknown.
Intended storage time	Device can maintain 4° C to 8° C through 24 hours	Currently indicated for up to 4 hours. Device testing demonstrates maintenance of 4° C to 8° C range through 12 hours.	No time within indication statement	Unspecified

Summary of Substantial Equivalence:

The design, intended use, principles of operation, and technological characteristics of the Sherpa Pak Kidney Transport System are substantially equivalent to the previously cleared Sherpa Pak Cardiac Transport System (K123326). The intended use of the subject device is the same as all the cited predicates and the labeled indications for use is similar for each device. Substantial equivalence is based upon descriptive characteristics of the various cited predicate devices and upon the testing conducted to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices in terms of its ability to safely store and transport a donor organ at a clinically acceptable temperature range to a recipient for transplantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Paragonix Technologies, Inc.
% Leo L. Basta
Owner
NorthStar Biomedical Associates
93 Benefit Street
Providence, RI 02904

Re: K133694
Trade/Device Name: Paragonix Sherpa Pak Kidney Transport System
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: May 15, 2014
Received: May 16, 2014

Dear Leo L. Basta,

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 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,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K133694

Device Name: Paragonix Sherpa Pak Kidney Transport System

Indications for Use:

The Sherpa Pak Kidney Transport System is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ.

The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.

Prescription Use: X AND/OR Over-The Counter Use:

(Per 21 CFR 801 Subpart D)..... (Per 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)

Herbert P. Lerner -S
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