



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

November 25, 2014

Paragonix Technologies, Inc.
% Mason Diamond
Regulatory Consultant
Texel Fortis, LLC
150 Levinberg Lane
Wayne, NJ 07470

Re: K143074
Trade/Device Name: Sherpa Pak Cardiac Transport System
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories
Regulatory Class: Class II
Product Code: MSB,
Dated: November 10, 2014
Received: November 13, 2014

Dear Mason Diamond,

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for

Benjamin Fisher

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Section 7.0

Indications for Use Statement

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Indications for Use

510(k) Number (if known): K143074

Device Name: **Paragonix Sherpa Pak Cardiac Transport System**

Indications For Use:

“The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart.

The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours.

Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.”

Prescription Use X
(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)

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Section 8

510(k) Summary

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

510(k) Summary

Paragonix Sherpa Pak Cardiac Transport System Kit

Submitter: Paragonix Technologies, Inc.
c/o Vaughn & Associates
639 Granite Street
Braintree, MA 02184

Contact Person: Mason W. Diamond, DDS
Texel Fortis, LLC
150 Levinberg Lane
Wayne, NJ 07470
Phone: 508-333-0108
Fax: 973-305-0213
masonwd@aol.com

Date Prepared: October 24, 2014

Trade Name: Paragonix Sherpa Cardiac Kidney Transport System

Classification Name: System and Accessories, Isolated Heart, Transport and Preservation

Regulation Number: 21 CFR 876.5880

Product Code: MSB

Predicate Devices: Sherpa Pak Cardiac Transport System (Paragonix Technologies, Inc) - K133432
Celsior Cold Storage Solution (SangStat Medical Corp) – K991594
Custodiol HTK (Dr Franz Köhler Chemie GmbH) – K032794

Device Description: The Paragonix Sherpa Pak Cardiac Transport System is a device intended to provide a safe, consistent method for cold ischemic storage and transport of donor hearts to recipients for transplantation. The Sherpa Pak 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 heart 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 in all respects.

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

The purpose for this change is to allow the Paragonix Sherpa Pak Cardiac Transport System to be distributed with any FDA-cleared, commercially-available preservation solution, as a Convenience Kit.

Intended Use: Organ storage and preservation for transplantation.

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

The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours.

Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

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.

Specifically, testing to demonstrate that the Sherpa Pak Cardiac Transport System provided a transport system robust enough to protect the donor organ during transport and maintained temperature throughout the duration of transport was included. Thermal qualification demonstrated the ability of the Sherpa Pak Cardiac Transport System to maintain the required temperature through 12 hours.

Submitter:
Paragonix Technologies, Inc.

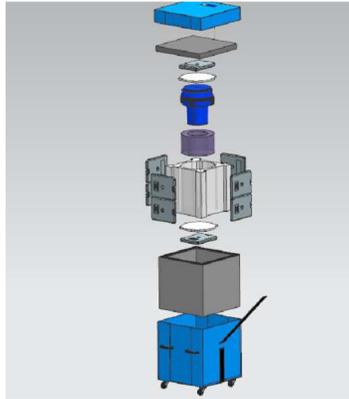
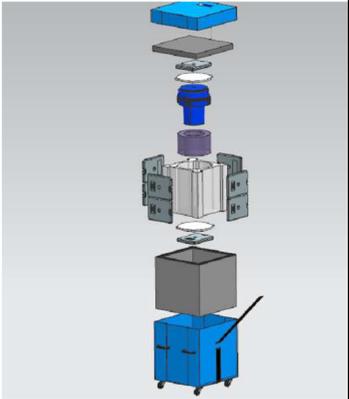
Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Device Characteristic Comparison

Characteristic	Proposed Sherpa Pak Cardiac Transport System [Modification]	Sherpa Pak Cardiac Transport System – K133432	Celsior – K991594	Custodiol HTK– K032794
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	<p>“The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart.</p> <p>The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours.</p> <p>Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.”</p>	<p>“The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart.</p> <p>The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours.</p> <p>Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.”</p>	<p>“Celsior is intended for flushing and cold storage of a heart at the time of its removal from a donor in preparation for storage, transportation, and eventual transplantation into a recipient.”</p>	<p>“Custodiol HTK Solution is indicated for perfusion and flushing donor kidneys, livers, and hearts prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.”</p>
Regulation Number	878.5880	878.5880	878.5880	878.5880
Product Code	MSB	MSB	MSB	MSB
Device Classification Name	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – Isolated kidney perfusion and transport system and accessories
Mode of Operation	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Characteristic	Proposed Sherpa Pak Cardiac Transport System [Modification]	Sherpa Pak Cardiac Transport System – K133432	Celsior – K991594	Custodiol HTK– K032794
Meets UNOS Policy 5¹	Yes	Yes	Yes	Yes
Organ container	Two rigid airtight containers one of which contains the cold storage solution in which the heart 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 Transporter System or the Avid custom procedure tray tub.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Transporter System or the Avid custom procedure tray tub.
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. Relies on transport system for type of cooling and maintenance of temperature.
System components	 <ul style="list-style-type: none"> • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels 	 <ul style="list-style-type: none"> • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels 	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).	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).

¹ <http://www.optn.transplant.hrsa.gov>

Submitter:
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Cardiac Transport System
Premarket Notification: Special 510(k)

Characteristic	Proposed Sherpa Pak Cardiac Transport System [Modification]	Sherpa Pak Cardiac Transport System – K133432	Celsior – K991594	Custodiol HTK–K032794
	<ul style="list-style-type: none"> • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell without connector • Temperature data logger • Timer • Plastic bags with cold storage solution to be used in combination with the Sherpa Pak Kidney Transporter System [supplied in a separate package]. 	<ul style="list-style-type: none"> • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell without connector • Temperature data logger • Timer 		
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.
Sterilization	Sherpa Pak, Sherpa Pak Shell, and Heart connector 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.	Sterilized.
Biocompatibility	Direct and indirect heart contact materials have been tested for biocompatibility.	Direct and indirect heart contact materials have been tested for biocompatibility.	Yes.	Yes.
Intended storage time	Up to 4 hours (clinical standard is 4-6 hours)	Up to 4 hours (clinical standard is 4-6 hours)	No time within indication statement	No time within indication statement

Submitter:
System
Paragonix Technologies, Inc.
510(k)

Paragonix Sherpa Pak Cardiac Transport

Premarket Notification: Special

Summary of Design

Changes:

The design, indications for use, principles of operation, technological characteristics, and packaging of the Sherpa Pak Cardiac Transport System are exactly the same as the previously cleared Sherpa Pak Cardiac Transport System (K133432). Sherpa Pak Cardiac Transport System is intended to be used with any preservation solution that is cleared by the FDA for use with hearts, and, therefore, the combined kitting of the Paragonix Sherpa Pak Cardiac Transport System and any FDA-Cleared preservation solution (i.e., Celsior, Custodiol HTK, etc.) falls within the current scope of use for the aforementioned devices. The purpose for this change is to allow the Paragonix Sherpa Pak Cardiac Transport System to be distributed with any FDA-cleared, commercially-available donor heart cold storage preservation solution, as a Convenience Kit. According to the FDA "Convenience Kits Interim Regulatory Guidance" (May 20, 1997), the Sherpa Pak Cardiac Transport System falls within the definition of a Convenience Kit. As a result, no further testing is required.