March 30, 2018

Paragonix Technologies, Inc.
% Leo L. Basta
Official Correspondent
Northstar Biomedical Associates
93 Benefit Street
Providence, RI 02904

Re: K180194
Trade/Device Name: SherpaPak Cardiac Transport System
SherpaPak Kidney Transport System
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated Kidney Perfusion and Transport System and Accessories
Regulatory Class: II
Product Code: MSB, KDN
Dated: January 22, 2018
Received: January 24, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180194

Device Name
SherpaPak Cardiac Transport System
SherpaPak Kidney Transport System

Indications for Use *(Describe)*
SherpaPak Cardiac Transport System

The SherpaPak 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 SherpaPak 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.

SherpaPak Kidney Transport System

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K180194
SherpaPak Cardiac Transport System
SherpaPak Kidney Transport System

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Contact Person: Leo Basta
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Date Prepared: March 30, 2018

Trade Name: SherpaPak Cardiac Transport System
SherpaPak Kidney Transport System

Classification Name: Isolated Kidney Perfusion and Transport System and Accessories

Classification: Class II

Regulation Number: 21 CFR 876.5880

Product Code: MSB and KDN

Predicate Devices: Sherpa Pak Cardiac Transport System (K133432)
And Sherpa Pak Kidney Transport System (K133694)

Device Description:
The SherpaPak Cardiac Transport System and SherpaPak Kidney Transport System result from modifications made to the cleared Sherpa Pak Cardiac Transport System and Sherpa Pak Kidney Transport System most recently cleared under K133432 and K133694, respectively. The principle of operation of the modified devices is identical to that of the cleared devices, namely, cold static storage and transportation of donor hearts (Cardiac version) or donor kidneys (Kidney version), using cleared preservation solutions specific to the organ type being transported. Further, the modified designs have the same indications for use and utilize the same technology as the predicate devices.

The subject SherpaPak design (cardiac and kidney) like its predecessor, consists of 1) outer transport shipper which contains within it various non-ice based temperature controlled packaging elements, 2) an inner and outer hard shell assembly (i.e. Sherpa Canister/Sherpa Shell) which provides a double, rigid barrier shipper in which the heart/kidney is immersed and suspended in a cold storage solution cleared for use in storing and transporting donor hearts/kidneys, and 3) a data logger that monitors and displays the temperature of the cold storage solution in which the heart/kidney is stored during transport.

The following modifications were made from the predicate to subject devices:

1. Change to the exterior shipping container to incorporate insulating capabilities using rigid EPS material,
2. Elimination of separate EPS and PIR panels which are no longer necessary to maintain temperature during preservation and transport (reducing system bulk),
3. Modification of the Phase Change Material (PCM) cooling packs and configuration used to maintain temperature during preservation and transport,
4. Direct measurement of cold storage solution temperature using a temperature probe inserted within the Sherpa Canister,
5. Modifications to the Sherpa Canister and Shell to a) incorporate the ability to transmit temperature data from the temperature probe to the data logger and ergonomic changes providing easier handling during use (e.g., handle on the Sherpa Shell lid), and
6. Ability to use a mobile app to see temperature during transport.

Intended Use:

Organ storage and preservation for transplantation.

Indications for Use:

SherpaPak Cardiac Transport System

The SherpaPak 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 SherpaPak 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.

SherpaPak Kidney Transport System

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

Functional Testing:

The premarket notification was submitted to implement modifications to the currently cleared Sherpa Pak Cardiac and Kidney Transport Systems. Testing performed related to the modifications made to the cleared devices included the following:

- Biocompatibility testing of any new materials that contact the body
  - The biocompatibility evaluation for the modified devices was conducted in accordance with International Standard ISO 10993-1: 2009 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests: Cytotoxicity, Sensitization, Irritation, Acute Systemic toxicity, Material Mediated Pyrogenicity, Hemocompatibility, and Genotoxicity testing
- Electrical Safety and EMC testing in conformance with
  - EN 60601-1: 2006 +A11:2011 + CORR.1:2006 + CORR.2:2007 + CORR.3: 2010 MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR SAFETY; EN 60601-1-6: 2010 + A1:2014 MEDICAL ELECTRICAL EQUIPMENT PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY; EN 62366:2007 + A1:2014 MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES
- Transportation Test
  - The purpose of this test was to evaluate the entire System when subjected to the rigors of transportation. The System was tested using a modified protocol per ASTM D4169-09. The protocol tested vibration and altitude stresses on the system.
- Thermal qualification

- The modified SherpaPak System is required to store and transport a donor heart (or kidney) in cold storage solution between 4°C - 8°C for up to 4 hours (cardiac) and 24 hours kidney). This test was performed to demonstrate the system could meet this specification.

- Helium Leak Testing
  - The purpose of this test was to evaluate the seal integrity of the organ container (Canister and Shell) that contains the donor organ and the cold storage solution. The Canister and Shell are both provided sterile and are intended to maintain sterility during transport of the donor heart in solution.

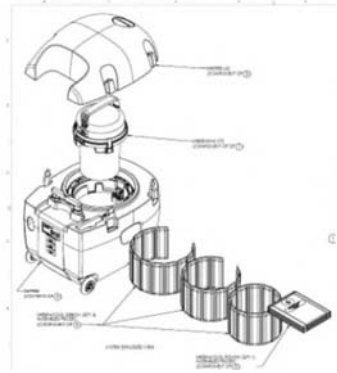
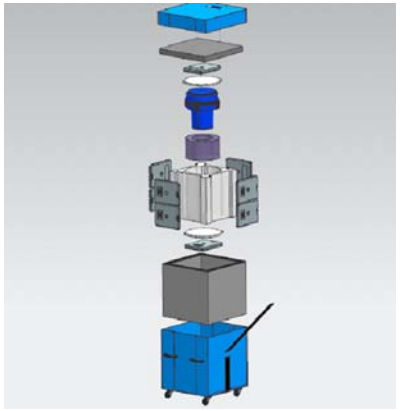
Comparison of Technological Characteristics with the Predicate Device

The following table compares the SherpaPak Cardiac Transport System and SherpaPak Kidney Transport System with the predicated devices.

Characteristic	Modified SherpaPak Cardiac/Kidney Transport System K180194	Sherpa Pak Cardiac Transport System Device and Sherpa Pak Kidney Transport System – K133432, K133694, respectively
Intended Use	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.
Indications for Use	***Cardiac*** The SherpPak 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 solution 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. ***Kidney*** The SherpaPak 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 the organ. The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.	***Cardiac*** The SherpPak 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 solution 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. ***Kidney*** 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 the organ. The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.
Regulation Number	878.5880	878.5880
Product Code	MSB (cardiac), KDN (kidney)	MSB (cardiac), KDN (kidney)

Characteristic	Modified SherpaPak Cardiac/Kidney Transport System K180194	Sherpa Pak Cardiac Transport System Device and Sherpa Pak Kidney Transport System – K133432, K133694, respectively
Device Classification Name	Device Classification Name – Isolated kidney perfusion and transport system and accessories And Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – Isolated kidney perfusion and transport system and accessories And Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation
Mode of Operation	Static cold ischemic storage	Static cold ischemic storage
Meets UNOS Policy 5[1]	Yes	Yes
Organ container	Two rigid airtight containers one of which contains the cold storage solution in which the organ is immersed. Material – Polycarbonate Inner Canister with temperature probe slot for direct temperature measurement of storage solution.	Two rigid airtight containers one of which contains the cold storage solution in which the heart is immersed. Material – Polycarbonate Outer Shell with slot for temperature probe for indirect temperature measurement of storage solution.
Cooling	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs.	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels

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

Characteristic	Modified SherpaPak Cardiac/Kidney Transport System K180194	Sherpa Pak Cardiac Transport System Device and Sherpa Pak Kidney Transport System – K133432, K133694, respectively
System components	 • Outer molded EPS Shipping container with wheels and extending handle • PCM Cold Pack Panels • Sherpa Pak and Sherpa Pak Shell • Temperature data logger • Mobile app to monitor temperature	 • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell • Temperature data logger • Separate Timer
Single Use/Reuse	Entire system is single use/patient only.	Entire system is single use/patient only.
Sterilization	Sherpa Pak, Sherpa Pak Shell, and Heart connector (cardiac version) are sterile. All other components are non-sterile.	Sherpa Pak, Sherpa Pak Shell, and Heart connector (cardiac version) are sterile. All other components are non-sterile.
Biocompatibility	Direct and indirect heart contact materials have been tested for biocompatibility.	Direct and indirect heart contact materials have been tested for biocompatibility.

Characteristic	Modified SherpaPak Cardiac/Kidney Transport System K180194	Sherpa Pak Cardiac Transport System Device and Sherpa Pak Kidney Transport System – K133432, K133694, respectively
Storage Temperature Duration	Device can maintain 4° C to 8° C through 44 hours.	Device can maintain 4° C to 8° C through 36 hours.

Conclusion:

The design, intended use, principles of operation, and technological characteristics of the SherpaPak Cardiac Transport System and SherpaPak Kidney Transport System are substantially equivalent to the previously cleared Sherpa Pak Cardiac Transport System and the Sherpa Pak Cardiac Transport System (K133432) and Sherpa Pak Kidney Transport System (K133694), respectively. All of the employed components are very similar to those of the cleared Sherpa Pak devices and utilize the same fundamental scientific technology. The modifications made were such to improve manufacturability and user ergonomics of the system and do not change the devices' intended use. Based upon the descriptive information provided and the testing conducted, the modified SherpaPak Cardiac and Kidney Transport Systems are substantially equivalent to their predicates.