October 23, 2024

Paragonix Technologies, Inc.
Lucas Churchill
Chief Innovation Officer
950 Winter Street, North
Waltham, MA 02451

Re: K234060
Trade/Device Name: KIDNEYvault Portable Renal Perfusion System
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: October 21, 2024
Received: October 21, 2024

Dear Lucas Churchill:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234060

Device Name

KIDNEYvault Portable Renal Perfusion System

Indications for Use *(Describe)*

The Paragonix KIDNEYvault Portable Renal Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ.

The Paragonix KIDNEYvault Portable Renal Perfusion System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours

Donor kidneys exceeding clinically accepted 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.

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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510k Summary

Paragonix Technologies' KidneyVault Device (K234060)

Submitter: Paragonix Technologies Inc.
950 Winter St, North
Waltham, MA 02451

Contact Person: Lucas Churchill
Paragonix Technologies, Inc.
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617.306.7219 (phone)
lucas@paragonixtechnologies.com

Date Prepared: August 14, 2024

Trade Name: KIDNEYvault Portable Renal Perfusion System

Classification Name: Isolated kidney perfusion and transport system and accessories

Classification: Class II

Regulation Number: 21 CFR § 876.5880

Product Code: KDN

Predicate Device: LifePort Perfusion Kidney Transporter (K021362)

Reference Devices: SherpaPak Kidney Transport System (SherpaPak KTS, K180194)

KIDNEY ASSIST – transport (K211333)

Device Description:

The KIDNEYvault Portable Renal Perfusion System (KIDNEYvault) device is designed to provide pulsatile perfusion of pre-chilled machine preservation solution through the kidney by means of a mechanical pump and closed fluid circuit integrated within the device and attached to the kidney. Its intended use and principle of operation are the same as the predicate device, LifePort Kidney Perfusion Transporter (K021362), while the differences in the technological characteristics from the predicate are supported by the literature, testing, and the

following reference devices: SherpaPak KTS and KIDNEY Assist. To maintain the chilled temperature of the machine preservation solution, the subject KIDNEYvault utilizes the same technology as the first reference device, SherpaPak KTS; whereas certain specifications for the subject device are based on the second reference device, KIDNEY Assist-transport.

The subject KIDNEYvault device consists of the following components:

1) KIDNEYvault SherpaCool Pouch and Ribbons – Phase Change Material (PCM) (identical to the first reference device) to maintain temperature of the cold machine preservation solution and kidney throughout transportation. The KIDNEYvault device maintains the temperature between 4°C to 8°C throughout preservation and transportation.

2) KIDNEYvault Canister Assembly – Proprietary hard shell, polycarbonate nested canister set for the packaging of the donor kidney within cold machine preservation solution and circulation of preservation solution through kidney vasculature.

   The Canister Assembly incorporates a closed fluid pathway and connections to the donor kidney that draws cold machine preservation solution from the Inner Canister and circulates it through the renal artery of the kidney and exits through the renal vein or ureter back into the Inner Canister.

3) KIDNEYvault Shipper - Outer transport shipper which comprises a protective and insulative package. The KIDNEYvault Shipper is a rigid, molded expanded polystyrene (EPS) insulative container into which the KIDNEYvault SherpaCool and KIDNEYvault Canister Assembly are placed. The maintenance of temperature of the donor kidney between 4°C to 8°C is assisted by the EPS insulation of the Shipper, providing insulation from the exterior environment to the interior components and KIDNEYvault SherpaCool.

   The KIDNEYvault Shipper incorporates a peristaltic pump used to circulate the machine preservation solution through the kidney vascular system. The pump is a peristaltic pump that circulates chilled machine preservation solution (drawn from the Inner Canister) into the renal

artery, through the kidney vasculature, and exiting back into the Inner Canister through the renal vein or ureter.

The KIDNEYvault Shipper includes a datalogger (connected to a temperature probe and pressure sensor) which records and displays the temperature of the machine preservation solution surrounding the donor kidney and the perfusion pressure within the fluid pathway.

4) KIDNEYvault Cannula – The cannula connects to the renal artery of the kidney and the fluid circuit of the KIDNEYvault. There are multiple sizes of round cannulas and oval cannulas for different kidney anatomies.

Intended Use:

Donor kidney preservation and transportation

Indications for Use:

The Paragonix KIDNEYvault Portable Renal Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ.

The Paragonix KIDNEYvault Portable Renal Perfusion System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.

Donor kidneys exceeding clinically accepted 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.

Technological Comparison with Predicate and Reference Devices

The following table compares the Paragonix KIDNEYvault device with the predicate and reference devices.

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Paragonix Technologies' KidneyVault Device (K234060)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device	Predicate Device	First Reference Device	Second Reference Device
	KIDNEYvault	**LifePort Perfusion Kidney Transporter (K021362)**	**SherpaPak Kidney Transport System (K180194)**	**KIDNEY ASSIST-transport (K211333)**
Intended Use	Kidney preservation and transportation.	Kidney preservation and transportation.	Kidney preservation and transportation.	Kidney preservation and transportation.
Indications for Use	The Paragonix KIDNEYvault Portable Renal Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ. The Paragonix KIDNEYvault Portable Renal Perfusion System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours. Donor kidneys exceeding clinically accepted 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.	LifePort Kidney Perfusion Transporter (KTR) is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient.	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.	The KIDNEY ASSIST-transport is intended to be used for the pulsatile hypothermic oxygenated machine perfusion of kidneys for the preservation, transport and eventual transplantation into a recipient.
Regulation Number	876.5880	876.5880	876.5880	876.5880
Product Code	KDN	KDN	KDN	KDN
Device Classification Name	Isolated kidney perfusion and transport system and accessories.	Isolated kidney perfusion and transport system and accessories.	Isolated kidney perfusion and transport system and accessories.	Isolated kidney perfusion and transport system and accessories.

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Paragonix Technologies' KidneyVault Device (K234060)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device	Predicate Device	First Reference Device	Second Reference Device
	KIDNEYvault	**LifePort Perfusion Kidney Transporter (K021362)**	**SherpaPak Kidney Transport System (K180194)**	**KIDNEY ASSIST-transport (K211333)**
Operating Principle	Hypothermic machine perfusion storage and transportation (i.e., HMP) of donor kidneys.	Hypothermic machine perfusion storage and transportation (i.e., HMP) of donor kidneys.	Static hypothermic storage (i.e., Static Cold Storage) of donor kidneys.	Oxygenated hypothermic machine perfusion storage and transportation (i.e., HMP) of donor kidneys.
Intended Organ Storage Time	Up to 24 hours.	Not expressly limited.	Through 24 hours.	Up to 24 hours.
Single Use	Entire system is single-use/single-patient only.	Organ contacting components are disposable. Reusable components for perfusion.	Entire system is single-use/single-patient only.	Organ contacting components are disposable. Reusable components for perfusion.
Meets UNOS Policy 16[1]	Yes	Yes	Yes	Yes
Shipper	Outer molded EPS Shipping container with wheels, extending handle, integrated mechanical perfusion pump, and integrated datalogger	Reusable transport system with incorporated mechanical perfusion pump and data display	Outer molded EPS Shipping container with wheels, extending handle, and integrated datalogger	Reusable transport system with incorporated mechanical perfusion pump and data display
Organ Container	Two single use, rigid, fluid-tight canisters; the inner of which contains the cold machine preservation solution in which the kidney is immersed. Organ container provides closed loop circuit for machine preservation of donor kidney.	Two single use, rigid containers, inner of which contains the cold machine preservation solution in which the kidney is immersed. Organ container provides closed loop circuit for machine preservation of donor kidney.	Two single use, rigid, fluid-tight canisters; the inner of which contains the cold storage solution in which the kidney is immersed.	Two single use, rigid containers. Inner container holds donor kidney and is submerged in the outer container containing cold machine preservation solution. Organ container provides closed loop circuit for machine preservation of donor kidney.
Preservation Temperature Regulation	4°-8° C using SherpaCool phase change material (PCM) cold packs.	0.5°-8° C using a mixture of ice and water.	4°-8° C using SherpaCool phase change material (PCM) cold packs.	2°-10° C using crushed ice.

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

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	KIDNEYvault	**LifePort Perfusion Kidney Transporter (K021362)**	**SherpaPak Kidney Transport System (K180194)**	**KIDNEY ASSIST-transport (K211333)**
Cannula	Various sizes and configurations to accommodate renal arteries of various diameters, kidneys with multiple renal arteries, and renal arteries with an aortic patch.	Various sizes and configurations to accommodate renal arteries of various diameters, kidneys with multiple renal arteries, and renal arteries with an aortic patch.	N/A	Various sizes and configurations to accommodate renal arteries of various diameters, kidneys with multiple renal arteries, and renal arteries with an aortic patch.
Mechanical Perfusion Pump	Peristaltic; Pulsatile perfusion; Fixed Speed. On/Off controls. Flow through donor kidney regulated by perfusion pressure. Not user configurable.	Peristaltic; Pulsatile perfusion. Flow through donor kidney regulated by perfusion pressure set by user.	N/A	Centrifugal; Pulsatile oxygenated perfusion. Flow through donor kidney regulated by perfusion pressure set by user.
Preservation Solution Capacity	1-2 Liters of hypothermic machine perfusion solution.	1 Liter of hypothermic machine perfusion solution.	4 Liters of hypothermic solution.	1 Liter of hypothermic machine perfusion solution.
Power	Alkaline batteries power datalogger and mechanical perfusion pump.	AC/DC; Portable with Li-ion Battery.	Alkaline batteries power datalogger.	AC/DC; Portable with Li-ion Battery.
Perfusion Pressure Limit	65mmHg	65mmHg	N/A	70mmHg
Operating Perfusion Pressure	0-50mmHg	10-65mmHg	N/A	0-50mmHg
Perfusion Pressure Regulation	Mechanically Controlled	Software Controlled	N/A	Software Controlled
Preservation Fluid	An FDA-cleared hypothermic machine perfusion solution for donor kidneys.	An FDA-cleared hypothermic machine perfusion solution for donor kidneys.	An FDA-cleared hypothermic solution for donor kidneys	An FDA-cleared hypothermic machine perfusion solution for donor kidneys.
Renal Flow Operating Range Measurement	0 mL/min to 150 mL/min	0 mL/min to 200 mL/min	N/A	0 mL/min to 250 mL/min
Dimensions	20.25" L x 16" W x 18.5" H	24" L x 14.5" W x 14" H	20.25" L x 16" W x 18.5" H	23.6" L x 15.3" W x 13.4" H

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Paragonix Technologies' KidneyVault Device (K234060)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device	Predicate Device	First Reference Device	Second Reference Device
	KIDNEYvault	**LifePort Perfusion Kidney Transporter (K021362)**	**SherpaPak Kidney Transport System (K180194)**	**KIDNEY ASSIST-transport (K211333)**
Air Bubble Prevention	Kidney is completely submerged in 1-2 Liters of hypothermic machine perfusion solution with air removed from closed nested canisters. Mechanical bubble trap eliminates air from perfusion circuit.	1 liter of hypothermic machine perfusion solution with room air above preservation solution in non-sealed disposable fluid circuit. Perfusion circuit is primed to remove air.	Kidney is completely submerged in up to 4 Liters of hypothermic preservation solution with air removed from inner canister.	1 liter of hypothermic machine perfusion solution with room air above preservation solution in non-sealed disposable fluid circuit. Perfusion circuit is primed to remove air.
Recording and Display	Temperature and pressure display integrated in device. Bluetooth Low Energy Enabled Datalogger with optional downloadable mobile app.	Flow, temperature, pressure, and renal resistance display integrated in device.	Temperature display integrated in device. Bluetooth Low Energy Enabled Datalogger with optional downloadable mobile app.	Flow, temperature, pressure, and renal resistance display integrated in device.

Summary of Literature

A literature search was conducted to analyze available clinical data on perfusion parameters for hypothermic machine perfusion and further assess available clinical literature for any evidence of limitations or specific parameters based on the type of donor kidneys (pediatric, extended criteria, etc.). All of the relevant publications reported perfusion pressures and flow rates within the subject device's specified pressure operating range. None clearly defined differential perfusion pressure or flow rate targets based on donor type.

Summary of Bench Testing:

- Biocompatibility testing in accordance with
  - ISO 10993-1: 2018 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process.
- Electrical Safety and EMC testing in accordance with the following standards:
  - IEC 60601-1:2005, AMD1:2012, AMD2:2020: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety & Essential Performance Testing
  - IEC 60601-1-2:2020 (ed. 4.1), Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
  - IEC 60601-1-6:2010, AMD1:2013, AMD2:2020: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
  - IEC 62366-1:2015, AMD1:2020: Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
  - FCC 47CFR Part 15.247:09: Radiated spurious emissions verification for a pre-certified radio continuous compliant when it incorporated into a host device
- KIDNEYvault Shipper Verification
  - Verification demonstrates the KIDNEYvault Shipper meets specifications beyond the intended organ storage time of 24 hours following exposure to worst-case shipping and handling.
- KIDNEYvault Canister Assembly Verification
  - Verification demonstrates the KIDNEYvault Canister Assembly meets specifications following exposure to sterilization and accelerated aging simulating real-time aging.

- KIDNEYvault Cannula Assembly Verification
  - Verification demonstrates the KIDNEYvault Cannula meets specifications following exposure to sterilization and accelerated aging simulating real-time aging.
- KIDNEYvault Sterile Barrier Validation
  - Verification demonstrates the ability of the KIDNEYvault sterile barrier system to maintain sterility following exposure to sterilization and accelerated aging simulating real-time aging.
- KIDNEYvault Performance Validation
  - Validation demonstrates the ability of the KIDNEYvault device to maintain hypothermic preservation and pulsatile perfusion under varying environmental and transportation conditions of the donor kidney beyond the intended organ storage time of 24 hours.

Conclusion

By design, the subject device is substantially equivalent to the predicate device based on equivalent intended use and principles of operation for pulsatile hypothermic machine perfusion within the donor kidney. The differences in the technological characteristics between the subject and predicate devices, as explained, verified/validated, and supported by the reference devices, do not lead to a different question of safety or effectiveness. The subject device is therefore substantially equivalent to the predicate device.