August 15, 2023

Paragonix Technologies
Nathan Yetton
Senior Director of Quality
639 Granite St., Suite 408
Braintree, Massachusetts 02184

Re: K223874
Trade/Device Name: BAROguard
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion and Transport System and Accessories
Regulatory Class: II
Product Code: KDN
Dated: July 17, 2023
Received: July 18, 2023

Dear Nathan Yetton:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Glenn B. Bell -S

for Gema Gonzalez, MS
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223874

Device Name
BAROguard

Indications for Use *(Describe)*
BAROguard™ is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs.

The intended organ storage time for BAROguard™ is up to 8 hours.

Donor lungs 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.

Note: Partial lungs can be transported via BAROguard™ by packaging lungs per institutional protocol and UNOS guidelines.

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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PARAGONIX	**005_Updated 510k Summary** Paragonix Technologies' BAROguard Device (K223874)

Submitter: Paragonix Technologies Inc.
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639 Granite Street
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Date Prepared: July 14, 2023

Trade Name: BAROguard

Classification Name: Isolated kidney perfusion and transport system and accessories

Classification: Class II

Regulation Number: 21 CFR § 876.5880

Product Code: KDN

Predicate Device: Paragonix LUNGguard (previously named, SherpaPak Lung Preservation System) - K192869

Device Description:

The subject BAROguard device results from modifications made to the cleared LUNGguard (previously named, SherpaPak Lung Preservation System) cleared under K192869. The subject BAROguard device consists of the following components:

1) BAROguard SherpaCool Pouches – Phase Change Material (PCM) pouches (identical to the predicate) to maintain temperature of the cold preservation solution and lung throughout transportation. The BAROguard device maintains the temperature between 4°C to 8°C identical to the predicate with the use SherpaCool pouches throughout preservation and transportation.

2) BAROguard Lung Containment Assembly – Nested lung containment bags for the packaging of donor lungs and preservation solution. BAROguard Lung Containment Assembly includes pneumatic connections to the donor lung in the inner-most bag, a pneumatic connection to the BAROguard Shipper Airway Pressure Management System, endotracheal connectors to connect the trachea of the donor lungs to the BAROguard Lung Containment Assembly, and tools for the secure attachment of the endotracheal connectors and closure of the BAROguard nested lung containment bags.

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

   The BAROguard Shipper incorporates an Airway Pressure Management System. The Airway Pressure Management System maintains the donor lung airway pressure when connected to the BAROguard Lung Containment Assembly.

   The BAROguard Shipper includes an off-the-shelf datalogger (connected to a temperature probe and airway pressure sensor) which monitors and displays the temperature of the solution surrounding the donor lungs and the airway pressure of the donor lungs.

Although the BAROguard is based on the predicate LUNGguard design, it also includes two new design elements:

- Incorporation of a sterile Lung Containment Assembly instead of use of off-the-shelf bags in K192869.
- Incorporation of an Airway Pressure Management System to maintain donor lung airway pressure during preservation and transportation.

PARAGONIX	005_Updated 510k Summary Paragonix Technologies' BAROguard Device (K223874)

Intended Use:

Donor lung preservation and transportation

Indications for Use:

The Paragonix BAROguard is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs.

The intended organ storage time for BAROguard is up to 8 hours.

Donor lungs 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.

Note: Partial lungs can be transported via BAROguard by packaging lungs per institutional protocol and UNOS guidelines.

Functional Testing:

- 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: 2018 "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, and Hemocompatibility
- Electrical Safety and EMC testing in accordance with the following standards:
  - IEC 60601-1:2005, AMD1:2012, AMD2:2020, IEC 60601-1-2:2014 (ed. 4.1), IEC 60601-1-6:2010, AMD1:2013, AMD2:2020, IEC 62366-1:2015, AMD1:2020, FCC 47CFR Part 15.247:09
- Thermal and Airway Pressure Validation
  - Validation demonstrates the ability of the BAROguard device to maintain hypothermic preservation and airway pressure of the donor lung beyond the intended organ storage time of 8 hours.

- BAROguard Shipper Verification
  - Verification demonstrates BAROguard Shipper meets specifications beyond the intended organ storage time of 8 hours following exposure to worst-case shipping and handling.
- Lung Containment Assembly Verification
  - Verification demonstrates BAROguard sterile Lung Containment Assembly meets specifications following exposure to sterilization and accelerated aging simulating real-time aging.
- BAROguard Sterile Packaging Validation
  - Verification demonstrates the ability of the BAROguard sterile barrier system to maintain sterility following exposure to sterilization and accelerated aging simulating real-time aging.
- 0.2 Micron Filter Validation
  - Validation demonstrates the bacterial retention of the filter used within the BAROguard device.
- ISO 18562-2
  - The average total particulate matter for the BAROgaurd device was found to be 10 µg/m3 for the entire 24 hours of continuous airflow through the system.

Technological Comparison with Predicate and Reference Device

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

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005_Updated 510k Summary

Paragonix Technologies' BAROguard Device (K223874)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Intended Use	Donor lung preservation and transportation.	Organ preservation and transportation.	To support treatment of adult Obstructive Sleep Apnea (OSA)	Identical to predicate (substantially equivalent)
Indications for Use	The Paragonix BAROguard is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs. The intended organ storage time for BAROguard is up to 8 hours. Donor lungs 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. Note: Partial lungs can be transported via BAROguard by packaging lungs per institutional protocol and UNOS guidelines.	The Paragonix SherpaPak Lung Preservation System (renamed as LUNGguard) is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs. The intended organ storage time for the Paragonix SherpaPak Lung Preservation system is up to 8 hours. Donor lungs 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. Note: Partial lungs can be transported via SherpaPak LPS by packaging lungs per institutional protocol and UNOS guidelines.	Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home. Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use.	Identical indications to predicate, with the only difference being the respective product names (substantially equivalent)
Regulation Number	876.5880	876.5880	868.5905	Identical to predicate (substantially equivalent)
Product Code	KDN	KDN	BZD	Identical to predicate (substantially equivalent)
Device Classification Name	Isolated kidney perfusion and transport system and accessories.	Isolated kidney perfusion and transport system and accessories.	Noncontinuous ventilator	Identical to predicate (substantially equivalent)

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Paragonix Technologies' BAROguard Device (K223874)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Operating Principle	Static hypothermic storage (i.e., Static Cold Storage) between 4° C to 8° C using FDA-cleared preservation solutions for lung organs, with management of donor lung airway pressure throughout preservation including during air transportation with continuous positive airway pressure of 12-15 cmH_2O (±1 cmH_2O) above ambient atmospheric pressure.	Static hypothermic storage (i.e., Static Cold Storage) between 4° C to 8° C using FDA cleared preservation solutions for lung organs. Lungs clinically inflated to static pressure of 12-15 cmH_2O prior to storage[1]	The system provides continuous positive airway pressure from 4 to 20 cmH_2O above the ambient atmospheric pressure.	Substantially equivalent to predicate The subject device provides the identical static hypothermic preservation as the predicate and also incorporates an Airway Pressure Management System with positive airway pressures similar to the reference device that is used in the same anatomy for the same physiological purpose. (See discussion following table on Substantial Equivalence in Operating Principle)
Intended Storage Time	Thermal qualification demonstrates the device can maintain 4° C to 8° C through the intended organ maximum cold ischemic time (CIT) with high and low temperature excursions (i.e., up to 8 hours).	Thermal qualification demonstrates the device can maintain 4° C to 8° C through the intended organ maximum cold ischemic time (CIT) with high and low temperature excursions (i.e., up to 8 hours).	N/A	Identical to predicate (substantially equivalent)
Single Use	Entire system is single-use/single-patient only.	Entire system is single-use/single-patient only.	Reusable system for single-patient use	Identical to predicate (substantially equivalent)
Meets UNOS Policy 16[2]	Yes	Yes	N/A	Identical to predicate (substantially equivalent)

[1] Copeland et al., Donor heart and lung procurement: A consensus statement, J Heart Lung Transplant 2020;39:501–517

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

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Paragonix Technologies' BAROguard Device (K223874)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Shipper	Outer molded EPS Shipping container with wheels, extending handle, integrated Airway Pressure Management System, and off-the-shelf datalogger	Outer molded EPS Shipping container with wheels, extending handle, and off-the-shelf datalogger	N/A	Substantially equivalent to predicate Identical EPS insulative shipper material and identical phase change (cooling) material are used for the subject and predicate devices. The subject device differs from predicate in that it incorporates an Airway Pressure Management System. (See discussion following table on Substantial Equivalence in Operating Principle) See "Monitor" row for details on the datalogger.

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Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Organ Container	Use of proprietary Lung Containment Assembly (including triple nested bags and endotracheal connector) which provides an air connection from the lungs to the airway pressure management system. The packaging is consistent with standard practice and OPTN policy. The nested bag assembly and all connections are provided sterile. Sterile components are gamma radiation sterilized to SAL 10^{-6}. All sterile components that come into direct contact or indirect via fluid contact with the donor lungs have been tested in accordance with FDA recognized standards.	Use of 3M Steri-Drape isolation bags cleared under K832318 (Product Code KGY, classification regulation 21 CFR §878.4100). The instructions for use for the subject devices recommend triple bagging the lungs which is consistent with standard practice and OPTN policy. The cleared, off-the-shelf organ isolation bags are provided sterile, and neither the packaging or labeling is modified from the OEM's.	N/A	Substantially equivalent Both subject and predicate devices each use three bags for transporting the lung organ. The BAROguard "nested-bag" assembly has undergone functional testing and biocompatibility testing to demonstrate that they achieve their intended effect and meet the same performance as triple bagging with off-the-shelf bags in the cleared device. (See 018_Updated Laboratory Bench Testing, subsection named Design Verification of Lung Containment Assembly for testing conducted on the nested bags)
Phase Change Material	Phase change material cold packs to maintain 4°-8° C temperature range for the intended transport time. SherpaCool made of phase change material: PCM Manufacturer: savERNG Cold Packs by Akuratemp (formerly RGEES), LLC	Phase change material cold packs to maintain 4°-8° C temperature range for the intended transport time. SherpaCool made of phase change material: PCM Manufacturer: savERNG Cold Packs by Akuratemp (formerly RGEES), LLC	N/A	Identical to predicate (substantially equivalent)

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Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Pressure Range	12-15 cmH_2O (±1 cmH_2O) preset within device, not user adjustable	Standard of care static pressure of 12-15 cmH_2O...the lungs should not be over- or underinflated."[3]	4-20 cm H2O (in 0.5 cm H2O increments), ≤30 cm H2O under single fault conditions	Substantially equivalent to predicate Paragonix observed pressures between 4-35 cmH_2O during simulated air transportation with the predicate device and has thus designed the subject device to address the excursions outside of the ISHLT-recommended range. The subject device has a tighter airway pressure range than reference device. (See discussion following table on Substantial Equivalence in Operating Principle)

[3] Copeland et al., Donor heart and lung procurement: A consensus statement, J Heart Lung Transplant 2020;39:501–517

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Paragonix Technologies' BAROguard Device (K223874)

Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Air source	Air in the operating room where the retrieved lungs were placed in the BAROguard This air in the internal chamber of the non-sterile BAROguard Shipper is drawn by the pneumatic pump and delivered to donor lungs through sterile organ containment assembly only when needed.	Donor lungs inflated and closed within operating room prior to loading into device	Room air delivered through non-sterile device with a blower	Substantially equivalent to predicate Similar to reference device. Both systems that provide air to airway are non-sterile. In addition, the subject device has a filter with higher filtration efficiency than the reference device. Further, the amount of air to be delivered to the lungs by the subject device is negligible when compared to the reference device. Therefore, the air source does not raise a different question of safety or effectiveness.
Air Filter Efficiency	0.2 Micron Filter has a log-reduction value (LRV) of B. diminuta greater than 8	N/A	Greater than 20% retentive for 10 micron particulates	Substantially equivalent to predicate See the prior discussion
Air Temperature	4°C-8°C	4°C-8°C	5°C-35°C	Identical to predicate Comparable air temperature range as reference device (Substantially equivalent)

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Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Operating Pressure	Sea Level to 8000ft (750-1015 hPa)	Sea Level to 8000ft (750-1015 hPa)	760 – 1060 hPa	Identical to predicate Comparable operating pressure range as reference device (Substantially equivalent)

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Table 1. Substantial Equivalence Comparison Table

Characteristic	Subject Device BAROguard (K223874)	Predicate Device SherpaPak Lung Preservation System (K192869)	Reference Device Auto CPAP System (K211155)	Substantial Equivalence Comparison
Monitoring	BlueTooth Low Energy Enabled Data Logger: • Off-the-shelf Data Logger from Onset Computer Corporation • Monitors temperature and pressure • BlueTooth capability to transfer temperature reading to iOS or Android device with HoboConnect App **Range:** -20° to 70° C (-4° to 158° F) **Temperature Accuracy:** ± 0.2° C from 0° to 50° C (± 0.4° F from 32° to 122° F) **Pressure Accuracy:** ± 0.3% of reading **Time Accuracy:** ±1 minute/month **Optional downloadable mobile app:** Allows for viewing temperature, pressure, and time elapsed over the mobile device. The app does not support, supplement, and/or augment the performance of the parent device. The BAROguard device is always accompanied by medical personnel during transport and the medical personnel can view information directly on the datalogger without use of the app.	BlueTooth Low Energy Enabled Data Logger: • Off-the-shelf Data Logger from Onset Computer Corporation • Monitors temperature • BlueTooth capability to transfer temperature reading to iOS or Android device with InTemp App **Range:** -30° to 70° C (-22° to 158° F) **Temperature Accuracy:** ± 0.5° C from 0° to 50° C (± 0.9° F from 32° to 122° F) **Pressure Accuracy:** N/A **Time Accuracy:** ±1 minute/month **Optional downloadable mobile app:** Allows for viewing temperature and time elapsed over the mobile device. The app does not support, supplement, and/or augment the performance of the parent device. The predicate is always accompanied by medical personnel during transport and the medical personnel can view information directly on the datalogger without use of the app.	**Pressure Accuracy:** ± (0.5 hPa +4%)	Substantially equivalent Monitoring of temperature is identical to predicate. Subject device incorporates a different model of data logger from the same vendor that allows for monitoring both temperature and pressure. Similar pressure accuracy to reference device (See 018_Updated Laboratory Bench Testing, subsection named Design Verification of BAROguard Shipper, for testing conducted on the data logger.)

Conclusion

By design, the subject device operates identically to the predicate when there is not a change in the ambient pressure and addresses a potential limitation associated with the use of the predicate device (and traditional ice coolers used within the Standard of Care) when there is a change in the ambient pressure. Testing confirms that the BAROguard meets the same performance specifications as the predicate device and also meets the requirements of maintaining lung airway pressure during air transportation.

The Airway Pressure Management System in the BAROguard device is similar to the pressure control systems reference the Auto CPAP System (K211155) for the maintenance of continuous positive airway pressure within the donor lung. The reference device is used in the same anatomical location (the airway) and for the same physiological purpose (maintaining a constant, set pressure within that airway above ambient atmospheric pressures) as the BAROguard device.

Based on the design and testing conducted, the subject BAROguard device is substantially equivalent to the predicate device.