January 20, 2022

Organ Assist Products B.V.
% Kathleen Johnson
President (Regulatory Affairs Consultant)
Medical Device Approvals, Inc.
104 E. Harrison Ave.
Fairfield, Iowa 52556

Re: K211333
Trade/Device Name: KIDNEY ASSIST-transport
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN
Dated: December 20, 2021
Received: December 20, 2021

Dear Kathleen Johnson:

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,

Gema Gonzalez
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)*
K211333

Device Name
KIDNEY ASSIST-transport

Indications for Use *(Describe)*
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.

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

Submitter of 510(k)

Owner's name: Organ Assist Products B.V. (an affiliation of XVIVO Perfusion AB)
Address: Bornholmstraat 84,
9723AZ Groningen
The Netherlands

Contact Person: Arjan van der Plaats
Title: Chief Technology Officer
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Official Correspondent: Kathleen Johnson
Title: Regulatory Affairs Consultant
Phone: 610-527-0585
E-mail: kathleen@mdapprovals.com

Date Prepared: April 30, 2021

Device Name

Trade/proprietary name: KIDNEY ASSIST-transport
Common/usual name: Transportable kidney perfusion system
Classification name: Isolated kidney perfusion and transport system and accessories (21 CFR §876.5880)
Product code: KDN
Regulatory Class: Class II

Device Description

The KIDNEY ASSIST-transport system of Organ Assist Products B.V. is a portable pump system that continuously allows hypothermic pulsatile perfusion of donor kidneys with oxygenated preservation solution during transport from donor to recipient in transplantation procedures. The system consists of the reusable KIDNEY ASSIST-transport device and a disposable KIDNEY ASSIST-transport perfusion set.
The characteristics of the KIDNEY ASSIST-transport are:

- Pulsatile oxygenated hypothermic machine perfusion of donor kidneys
- Transportable hypothermic machine perfusion technique
- Hypothermic preservation and reconditioning device
- Improved preservation compared to cold storage in DBD, ECD and DCD
- Easy to install disposable perfusion set

The KIDNEY ASSIST-transport device is a thermo isolated enclosure wherein the kidneys are cooled passively by ice and a separate compartment holding the electronics, batteries and a dedicated medical oxygen cylinder. The device has sufficient battery power, holds enough oxygen and ice for an application period of 24 hours of hypothermic oxygenated perfusion. Pulsatile perfusion is generated by a rotary pump driven by an electromotor and is pressure controlled. User-friendly firmware allows the user to change perfusion parameters. Settings and results of the perfusion measurements are numerically displayed on the top of the enclosure.
The single-use disposable KIDNEY ASSIST-transport perfusion set contains an easy to install preassembled perfusion cartridge for use in combination with the KIDNEY ASSIST-transport device. The purpose of the KIDNEY ASSIST-transport Perfusion Set is to perfuse human organs to be transplanted with an approved pump perfusion solution. Its set contains a reservoir, kidney holder, cannula, oxygenator, pump head, pressure sensor and compatible tubing. Pulsatile perfusion is maintained by the centrifugal pump head, pulsating the perfusion

solution from the reservoir through the oxygenator to the kidney in the kidney holder in the reservoir. Oxygenation is performed by the hollow fiber membrane oxygenator which facilitates the gas exchange with the perfusion solution. All kidneys will be perfused with University of Wisconsin Machine Perfusion Solution (UW-MP).
KIDNEY ASSIST-transport allows transportable machine perfusion preservation to bridge the timespan between procurement and transplantation of kidneys.

Application period

The 'KIDNEY ASSIST-transport' is a portable pump system that continuously allows hypothermic pulsatile perfusion of donor kidneys with oxygenated preservation solution during transport from donor to recipient in transplantation procedures for a period up to 24 hours.

Indications for Use

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.

Legally Marketed Predicate Device (K111521)

The KIDNEY ASSIST-transport (KAt) has been shown to be substantially equivalent to the legally marketed predicate device:

Trade/proprietary name: Waves (Waters Medical Systems LLC)

Common name:	Renal Preservation Systems
Classification name:	Isolated kidney perfusion and transport system and accessories (21 CFR §876.5880)
Product code:	KDN
Regulatory Class:	Class II
510(k) number:	K111521

Substantial equivalence summary

The KIDNEY ASSIST-transport can be considered substantial equivalent to the legally marketed predicate device (K111521, Waves system manufactured by Waters Medical Systems LLC).

A detailed comparison overview is presented below.

	Subject device: KIDNEY ASSIST-transport	**Predicate device:** Waves
		
Manufacturer	Organ Assist Products b.v.	Waters Medical Systems LLC
Registration	FDA 510(k): pending as per this submission	FDA 510(k): K111521
Intended use	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.	The Waves device is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transport and eventual transplantation into a recipient.
Configuration	Device in combination with sterile disposable set.	Device in combination with sterile disposable set.
Sterilization	Ethylene Oxide (ISO 11135)	Ethylene Oxide (ISO 11135)
Materials	Validated against ISO 10993	Validated against ISO 10993
Perfusion pump	Centrifugal pump	Displacement pump
Perfusion mode	Pulsatile	Pulsatile
Perfusion control	Pressure control, automated control features	Pressure control, automated control features
Software	Validated Embedded software and user interface (watch dog safety)	Validated Embedded software and user interface (watch dog safety)
Coolant	Crushed ice (6 L)	Crushed ice and water (5 L)
Power source	Battery 4x 11.1 V Li-ion or auxiliary power	Battery 4x 11.1 V Li-ion or auxiliary power
Perfusion rates	Pressure: 0-50 mmHg Flow: 0-250 mL/min Temp: 2°C -10°C	Pressure: 0-100 mmHg Flow: 0-250 mL/min Temp: 3°C-10°C
Duration	Up to 24 hours	Up to 24 hours with extra ice filling
Perfusate	Hypothermic machine perfusion solution	Hypothermic machine perfusion solution
Oxygenation	Medical oxygen 100 mL/min gas flow Hollow fibre oxygenator	Air or other gas mixtures Up to 1.5-2 L/min gas flow Silicone membrane oxygenator
Dimensions	23.6”x15.3”x13.4” 600mm x 390mm x 340mm	25.5”x16.25”x13.25” (648 mm x 413 mm x 337 mm)
Weight	55.8 lbs (25.3 kg)	57 lbs (26 kg)
Storage conditions	T: 5 - 40°C H: 5 - 85 %RH P: 50 to 106 kPa	T: 0°C tot 40°C H: 0-95% P: 94 to 101 kPa

Intended use

Both KIDNEY ASSIST-transport and the predicate device (K111521) are intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transport, and eventual transplantation into a recipient. Both systems oxygenate the cold perfusion solution that is perfused through the kidney; however, this is not included in the Intended Use statement of WAVES. For KIDNEY ASSIST-transport, the oxygenation intention is included for clarification.

Principle of Operation
Principle of operation is equivalent. Both KIDNEY ASSIST-transport and the predicate device (K111521) consist of a pump unit and a single-use disposable perfusion set/cassette. UW-MP solution is pumped through the kidney while being cooled passively by ice and oxygenated through an oxygenator. Perfusion parameters (pressure, flow, resistance and temperature) are continuously monitored, displayed and stored, safeguarded by an alarm system. The systems incorporate embedded software for user interface and safety and control mechanisms.

Configuration characteristics
Both KIDNEY ASSIST-transport and the predicate device (K111521) are comprised of reusable control/pump unit in combination with a single-use sterile perfusion set/cassette.

Perfusion Characteristics
Both KIDNEY ASSIST-transport and the predicate device (K111521) provide pressure-controlled pulsatile perfusion to the kidney. Perfusion characteristics on pressure, flow and temperature are similar. The predicate device (K111521) WAVES allows a higher user-set pressure than the KIDNEY ASSIST-transport (100 mmHg vs 50 mmHg). In most clinical trials a mean pressure of 25 mmHg is used and demonstrated safety and efficacy of the technology. Therefore, the 50-mmHg limit in the KIDNEY ASSIST-transport does not induce new safety and effectiveness questions.
In addition, the predicate device (K111521) uses a displacement pump, where the KIDNEY ASSIST-transport incorporates a centrifugal pump to provide perfusion to the kidney. Since the perfusion parameters (pulsatile pressure and flow) are similar, this has no influence on the perfusion reaching the kidney. In principle, the centrifugal pump is considered a safer alternative for the displacement pump with respect to pressure build as it is an open pump system. Application period of both devices is 24 hours.

Cooling characteristics
Both KIDNEY ASSIST-transport and the predicate device (K111521) provides cooling by melting ice that is added to the insulated device.

Power source characteristics
Power source is identical in both systems: 4 Li-ion batteries, or auxiliary power supply can be used. The WAVES batteries are automatically charged while the device is on auxiliary power.
For the KIDNEY ASSIST-transport, the batteries must be charged using an external charger. As this means that less electrical power is needed inside the device, this situation is considered safer.

Oxygenation characteristics
Both KIDNEY ASSIST-transport and the predicate device (K111521) incorporate oxygenation of the cold perfusion solution that is pumped through the kidney. Both systems actively oxygenated the solution by means of an oxygenator that is part of the sterile single-use perfusion set/cassette. The oxygenator is part of the preassembled single-use sterile perfusion set.
Both systems use oxygen to oxygenate, where the WAVES also allows other gas mixtures.

Performance Data

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on KIDNEY ASSIST-transport. The system complies with the IEC 60601-1:2012 Edition 3.1, ANSI/AAMI ES60601-1:2005/(R)2012 standards for safety and the IEC 60601-1-2:2007 + AC:2010 standard for EMC.

Software

The KIDNEY ASSIST-transport contains software that shows compliance with IEC 62304:2006. The software for this device is classified as IEC 62304 Class B software and is considered as a “major” level of concern in the US.

Biocompatibility testing

The biocompatibility evaluation for the KIDNEY ASSIST-transport was conducted and shows compliance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process."

Human factors and usability

The usability evaluation is conducted on the KIDNEY ASSIST-transport. The system complies with the IEC 62366:2008 application of usability engineering to medical devices and ANSI/AAMI HE75 human factors engineering – design of medical devices.

Sterility

The sterility evaluation is conducted on the KIDNEY ASSIST-transport Perfusion set. The system complies with the ISO 11135:2014 for Ethylene Oxide sterilization of health-care products (SAL 10^{-6}) and ISO 10993-7:2008 for Ethylene oxide sterilization residuals.

Packaging and shelf life

Packaging for the sterile components complies with ISO 11607:2019 packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Shelf life for the sterile components complies with ASTM F 1980-16:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Bench testing

Performance testing -Bench include tests on functional performance, transport and storage validation and usability validation for the complete system.

Investigator Initiated Clinical Data

The published data of an investigator-initiated clinical study supports the claimed Performance and benefit of the KIDNEY ASSIST-transport. The KIDNEY ASSIST-transport provides safe hypothermic machine perfusion of kidneys, while adding beneficial oxygen during perfusion.
In detail, the objective of the investigator-initiated clinical study was to investigate the effects of oxygenation in HMP (hypothermic machine perfusion). Following standard organ procurement, kidney pairs (donors aged 50 or older, 38 % Female and 62 % Male) were cannulated and connected to the KIDNEY ASSIST-transport and perfused with UW-MP solution. Kidney pairs were randomly assigned to oxygenated ($HMPO_2$) or non-oxygenated (HMP) perfusion in a paired design. In total 106 recipients were present in each study arm and followed one year post transplantation. Baseline characteristics were similar in both groups ($HMPO_2$: Age 60 years on average, 35 % Female, 65 % Male; HMP: Age 61 years on average, 37 % Female, 63 % Male). No data on ethnicity or race were reported.
The study results show that the addition of oxygen to HMP improves the outcomes compared to standard non-oxygenated HMP on kidney function and graft survival at 1 year after transplantation. $HMPO_2$ significantly reduces the number of severe post-operative complications (including (S)AE) and even leads to a drastic 44% fewer rejections of the kidney after transplantation.

Conclusion

Based on the intended use, indications for use, principle of operation and overall technological characteristics the KIDNEY ASSIST-transport has been shown to be substantially equivalent to the predicate device (K111521). Results of validation (including performance data) did not raise any questions on safety and effectiveness. It is concluded that the KIDNEY ASSIST-transport has been shown to be substantially equivalent to the legally marketed predicate device (K111521).