June 14, 2022

Institut Georges Lopez
Matthieu Prouteau
Director of Quality Affairs and Regulatory Affairs
Parc Tertiaire du Bois Dieu
RN6 - 1 Allee des Chevreuils
Lissieu, 69380
France

Re: K221386
Trade/Device Name: PERF-GEN Pulsatile Perfusion Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDL
Dated: May 6, 2022
Received: May 13, 2022

Dear Matthieu Prouteau:

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)*

Device Name
PERF-GEN Pulsatile Perfusion Solution

Indications for Use *(Describe)*
The PERF-GEN Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As Required by 21 CFR 807.92]

Written on June, 14 2022

I. Submitter:

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69380 Lissieu
France
Telephone: +33 437 646 332
Official Contact: Matthieu Prouteau – Director of Quality and Regulatory Affairs

II. Device Information

Trade Name:	PERF-GEN Pulsatile Perfusion Solution
Common Name:	Pulsatile Perfusion Solution
Regulation Description:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Class:	Class II
Product Code:	KDL

III. Predicate Devices Identification

PERF-GEN Pulsatile Perfusion Solution – Waters Instruments, Inc. – K121736

IV. Device Description

Institut Georges Lopez manufactures the PERF-GEN Pulsatile Perfusion Solution according to the solution pioneered at the University of Wisconsin by Dr Folkert O. Belzer, often referred to as "Belzer-MPS solution" used as kidney flushing and perfusion storage solution.
The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

The PERF-GEN Pulsatile Perfusion Solution is a clear to light yellow, sterile, non-pyrogenic solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. PERF-GEN Pulsatile Perfusion Solution has an osmolality of 300 mOsm/kg, a total sodium concentration of 100 mmol/L, a total potassium concentration of 25 mmol/L and a pH of 7.4 at room temperature.
The solution is packaged in 1-liter bags with a shelf life of 18 months.

The PERF-GEN Pulsatile Perfusion Solution is used at hospital by health professionals. The PERF-GEN Pulsatile Perfusion Solution must be cooled to +2°C and +8°C (35.6-46.5°F) prior to use. The cold solution is used for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys.

V. Indications for Use

The PERF-GEN Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

VI. Comparison of Technological Characteristics

The PERF-GEN Pulsatile Perfusion Solution received substantial equivalence determination after submission premarket notification (510(k) number K121736). Modified PERF-GEN Pulsatile Perfusion Solution is an extension of shelf life and storage conditions from the predicate.

The subject device PERF-GEN Pulsatile Perfusion Solution is labeled as sterile with a 18 months shelf life at 2-25°C whereas the predicate solution with a 12 months shelf life at 2-8°C. However, both solutions must be cooled to 2-8°C and do not need to be filtered before use.

The PERF-GEN Pulsatile Perfusion Solution is substantially equivalent to the predicate device.
The subject device has the same intended use, indication for use and the principle of operation as the predicate device. The subject and predicate have the same pH, osmolality, and chemical composition based on Belzer MPS solution.

The subject and predicate device are sterile, single use, non-pyrogenic and transparent solutions. Both solutions are sterilized by filtration and aseptically filled in similar design dispensing bags (3 ports) and made in EVA as fluid contact layer.

The following table provides a comparison of attributes between the subject device and the predicate devices:

	Subject Device	**Primary Predicate**	**Comparison**
Device	PERF-GEN Pulsatile Perfusion Solution	PERF-GEN Pulsatile Perfusion Solution	
510(k) Number	K221386	K121736	
Manufacturer	Institut Georges Lopez, France	Institut Georges Lopez, France	-
Classification & Product Code	876.5880, KDL	876.5880, KDL	Same
Device Classification Name	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories	Same
Device Description	The PERF-GEN Pulsatile Perfusion Solution is a clear to light yellow, sterile and non-pyrogenic solution.	The PERF-GEN Pulsatile Perfusion Solution is a clear to light yellow, sterile and non-pyrogenic solution.	Same
Format	The solution is packaged in 1-liter bags	The solution is packaged in 1-liter bags	Same

	Subject Device	Primary Predicate	Comparison
Intended use	The PERF-GEN Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.	The PERF-GEN Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.	Same
Solution Type	Extracellular Na+ 100 mmol/L K+ 25 mmol/L	Extracellular Na+ 100 mmol/L K+ 25 mmol/L	Same
Composition	Calcium Chloride Dihydrate (0.068 g/L) ; Sodium gluconate (17.45 g/L) ; Adenine (0.68 g/L) ; Potassium Phosphate monobasic (3.4 g/L) ; Pentafraction (HES) (50 g/L) ; Magnesium gluconate (1.13 g/L) – HEPES (2.38 g/L) - Glucose (1.80 g/L) ; Glutathione (0.92 g/L) - Ribose (0.75 g/L) ; Mannitol (5.4 g/L) ; Sodium Hydroxide (qs pH 7.4) - Water for injection (qs 1 litre)	Calcium Chloride Dihydrate (0.068 g/L) ; Sodium gluconate (17.45 g/L) ; Adenine (0.68 g/L) ; Potassium Phosphate monobasic (3.4 g/L) ; Pentafraction (HES) (50 g/L) ; Magnesium gluconate (1.13 g/L) – HEPES (2.38 g/L) - Glucose (1.80 g/L) ; Glutathione (0.92 g/L) - Ribose (0.75 g/L) ; Mannitol (5.4 g/L) ; Sodium Hydroxide (0.70 g/L) - Water for injection (qs 1 litre)	Same
pH at room temperature	7.4	7.4	Same
Osmolality	300 mOsm/Kg	300 mOsm/Kg	Same
Sterility	Sterile solution	Sterile solution	Same
Sterilization Method	Aseptic filtration (sterile A)	Aseptic filtration (sterile A)	Same
Single use	Yes	Yes	Same
Filtration required before use?	No	No	Same
Dispensing bag	Dispensing bags are made of ethylene-vinyl acetate (EVA) as fluid contact layer, with 3 tubing connections (ports)	Dispensing bags are made of ethylene-vinyl acetate (EVA) as fluid contact layer, with 3 tubing connections (ports)	Same
Shelf life	18 months (1.5 years)	12 months (1 year)	Shelf life Extension from predicate.
Storage Condition	Room temperature (2-25°C) (35.6° - 77°F)	Room temperature (2-8°C) (35.6° - 46.4°F)	Storage conditions extension from predicate.
Pre-use conditions	Cool at 2-8°C (35.6° - 46.5°F)	Cool at 2-8°C (35.6° - 46.5°F)	Same

VII. Summary of Non-Clinical Testing

No performance standards have been established by FDA for the PERF-GEN Pulsatile Perfusion Solution.

The following tests were performed to demonstrate safety based on current industry standards:

- The PERF-GEN Pulsatile Perfusion Solution is supplied sterile and non-pyrogenic in order to assure safety for transplant recipients. The validation of the sterilizing filtration and aseptic filling process were carried out according to ISO 13408-1 and ISO 13408-2.

- The biomaterial safety of the PERF-GEN Pulsatile Perfusion Solution has been evaluated through ISO 10993 compliant testing, which included cytotoxicity test, skin sensitization test in guinea pigs, primary skin irritation, hemolysis test and acute systemic toxicity test in mice. Results of this testing, showed the PERF-GEN Pulsatile Perfusion Solution is safe for the intended biocontact.

- The stability testing has showed that aging of test articles at the recommended storage conditions of 2-25°C (35.6° - 77°F) does not affect the product specifications for the PERF-GEN Pulsatile Perfusion Solution labeled with 18 months shelf life.

The results of these tests indicate that PERF-GEN Pulsatile Perfusion Solution is substantially equivalent to the predicate device.

VIII. Conclusion

The technological differences between the subject and predicate devices were evaluated through non-clinical testing. The results of these tests demonstrated that the subject device does not raise new issues of safety and effectiveness compared to the predicate device. The indications for use, technological characteristics, and performance characteristics of the PERF-GEN Pulsatile Perfusion Solution stored for up to 18 months at 2-25°C (35.6° - 77°F) assessed to be substantially equivalent to the predicate device.