June 14, 2022

Institut Georges Lopez
Matthieu Prouteau
Director of Quality Affairs and Regulatory Affairs
Parc Tertiaire du Bois Dieu
RN 6 - 1 Allee des Chevreuils
Lissieu, 69380
France

Re: K221387
Trade/Device Name: BEL-GEN Cold Storage 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)*
K221387

Device Name
BEL-GEN Cold Storage Solution

Indications for Use *(Describe)*
The BEL-GEN Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ 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.

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510(k) Summary

[As Required by 21 CFR 807.92]

Written on June, 14 2022

I. Submitter:

Institut Georges Lopez (IGL)
Parc Tertiaire du Bois Dieu
RN6 – 1 allée des Chevreuils
69380 Lissieu
France
Telephone: +33 437 646 332
Official Contact: Matthieu Prouteau – Director of Quality and Regulatory Affairs

II. Device Information

Trade Name:	BEL-GEN Cold Storage Solution
Common Name:	Cold Storage Solution
Regulation Description:	Isolated kidney perfusion and transport system and accessories
Regulation Number:	21 CFR 876.5880
Class:	Class II
Product Code:	KDL, KDN

III. Predicate Device Identification

Primary predicate: BEL-GEN Cold Storage Solution – Waters Instruments, Inc. – K121618
Secondary predicate: CoStorSol® - Preservation Solution Inc. – K091245

IV. Device Description

Institut Georges Lopez manufactures the BEL-GEN Cold Storage Solution according to the solution pioneered at the University of Wisconsin by Dr Folkert O. Belzer, often referred to as "Belzer UW solution". The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and phosphoric compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

The BEL-GEN Cold Storage Solution is a clear to light yellow single use, sterile and non-pyrogenic solution. BEL-GEN Cold Storage Solution has an osmolality of 320 mOsm/kg, a total sodium concentration of 29 mmol/L, a total potassium concentration of 125 mmol/L and a pH of 7.4 at room temperature.
The solution is packaged in 1-liter or 2-liter bags with a shelf life of 2 years.

The BEL-GEN Cold Storage solution is used at hospital by health professionals. The BEL-GEN Cold Storage solution must be cooled to +2°C and +6°C (36° and 43°F) prior to use The cold solution is used to flush the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vasculature during hypothermic storage and transportation to cool the organ and lower its metabolic requirements.

V. Indications for Use

The BEL-GEN Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

VI. Comparison of Technological Characteristics

The BEL-GEN Cold Storage Solution received substantial equivalence determination after submission premarket notification (510(k) number K121618). Modified BEL-GEN Cold Storage Solution is an addition of packaging size, an extension of shelf life and storage conditions from the primary predicate.

The subject device BEL-GEN Cold Storage Solution and secondary predicate are labeled as sterile with a 2-year shelf life at 2-25°C whereas the primary predicate solution with a 1 year shelf life at 2-8°C. However, all three Solutions must be cooled to 2-6°C and do not need to be filtered before use.

BEL-GEN Cold Storage Solution is substantially equivalent to primary and secondary predicate devices. The subject device has the same intended use, indication for use and the principle of operation as predicate devices. All three solutions have the same pH, osmolality, and chemical composition based on Belzer UW solution (except for Hydrochloric acid indicated in primary predicate and not necessary to adjust the pH at 7.4).

The subject and the both predicate devices are sterile, single use, non-pyrogenic and transparent solutions. All three solutions are sterilized by filtration and aseptically filled in similar design dispensing bags (3 ports) and made of 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	Secondary Predicate	Comparison
Device	BEL-GEN Cold Storage Solution	BEL-GEN Cold Storage Solution	CoStorSol®	
510(k) Number	K221387	K121618	K091245	
Manufacturer	Institut Georges Lopez, France	Institut Georges Lopez, France	Preservation Solutions, Inc. WI, USA	NA
Classification & Product Code	876.5880, KDL, KDN	876.5880, KDL, KDN	876.5880, KDN	Same, except for secondary predicate
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	Same
Device Description	The BEL-GEN Cold Storage Solution is a clear to light yellow, sterile and non-pyrogenic solution.	The BEL-GEN Cold Storage Solution is a clear to light yellow, sterile and non-pyrogenic solution.	CoStorSol® is a clear to light yellow, sterile and non-pyrogenic solution.	Same

	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Format	The solution is packaged in 1-liter and 2-liter bags	The solution is packaged in 1-liter bags	The solution is packaged in 1-liter bags	Similar The 2-liter format is added for the subject device
Intended use	The BEL-GEN Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.	The BEL-GEN Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.	CoStorSol ® is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient	Same
Solution Type	Intracellular Na+ 29 mmol/L K+ 125 mmol/L	Intracellular Na+ 29 mmol/L K+ 125 mmol/L	Intracellular Na+ 29 mmol/L K+ 125 mmol/L	Same
Composition	Pentafraction (HES) (50 g/L) ; Lactobionic acid (35.83 g/L) ; Potassium Phosphate monobasic (3.4 g/L) ; Magnesium Sulfate heptahydrate (1.23 g/L) ; Raffinose pentahydrate (17.83 g/L) ; Adenosine (1.34 g/L) Allopurinol (0.136 g/L) ; Glutathione (0.922 g/L) ; Potassium Hydroxide (5.61 g/L) ; Sodium Hydroxide (qs pH 7.4) Water for injection (qs 1 Litre)	Pentafraction (HES) (50 g/L) ; Lactobionic acid (35.83 g/L) ; Potassium Phosphate monobasic (3.4 g/L) ; Magnesium Sulfate heptahydrate (1.23 g/L) ; Raffinose pentahydrate (17.83 g/L) ; Adenosine (1.34 g/L) Allopurinol (0.136 g/L) ; Glutathione (0.922 g/L) ; Potassium Hydroxide (5.61 g/L) ; Sodium Hydroxide / Hydrochloric acid (qs pH 7.4) Water for injection (qs 1 Litre)	Pentafraction (HES) (50 g/L) ; Lactobionic acid (35.83 g/L) ; Potassium Phosphate monobasic (3.4 g/L) ; Magnesium Sulfate heptahydrate (1.23 g/L) ; Raffinose pentahydrate (17.83 g/L) ; Adenosine (1.34 g/L) Allopurinol (0.136 g/L) ; Glutathione (0.922 g/L) ; Potassium Hydroxide (5.61 g/L) ; Sodium Hydroxide(qs pH 7.4) Water for injection (qs 1 Litre)	Same as secondary predicate. Similar to primary predicate
pH at room temperature	7.4	7.4	7.4	Same
Osmolality	320 mOsm/Kg	320 mOsm/Kg	320 mOsm/Kg	Same
Sterility	Sterile solution	Sterile solution	Sterile solution	Same
Sterilization Method	Aseptic filtration (sterile A)	Aseptic filtration (sterile A)	Aseptic filtration (sterile A)	Same
Single use	Yes	Yes	Yes	Same

	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Filtration required before use?	No	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)	Dispensing bags are made of ethylene-vinyl acetate (EVA) as fluid contact layer, with 3 tubing connections (ports)	Same
Shelf life	24 months (2 years)	12 months (1 year)	24 months (2 years)	Same as secondary predicate. Shelf life Extension from primary predicate.
Storage Condition	Room temperature (2-25°C) (35.6° - 77°F)	Room temperature (2-8°C) (35.6° - 46.4°F)	Room temperature (2-25°C) (35.6° - 77°F)	Same as secondary predicate. Storage conditions extension from primary predicate.
Pre-use conditions	Cool at 2-6°C	Cool at 2-6°C	Cool at 2-6°C	Same

VII. Summary of Non-Clinical Testing

No performance standards have been established by FDA for the BEL-GEN Cold Storage Solution.

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

- The BEL-GEN Cold Storage 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 BEL-GEN Cold Storage 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 BEL-GEN Cold Storage 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 BEL-GEN Cold Storage Solution labeled with 2-year shelf life.

The results of these tests indicate that BEL-GEN Cold Storage Solution is substantially equivalent to the predicate devices.

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 devices. The indications for use, technological characteristics, and performance characteristics of BEL-GEN Cold Storage Solution stored for up to 2 years at 2-25°C (35.6° - 77°F) assessed to be substantially equivalent to the predicate devices.