March 31, 2025

Bridge to Life Ltd
Mark Harper
Compliance Manager
707 Skokie Boulevard, Suite 340
Northbrook, Illinois 60062

Re: K243384
Trade/Device Name: Belzer UW® Cold Storage Solution (BTLBUW-001)
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN, KDL
Dated: February 19, 2025
Received: February 19, 2025

Dear Mark Harper:

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,

Gema Gonzalez -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.

510(k) Number *(if known)*
K243384

Device Name
Belzer UW® Cold Storage Solution (BTLBUW-001)

Indications for Use *(Describe)*
Belzer UW® Cold Storage Solution (BTLBUW-001) is indicated 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. Belzer UW® Cold Storage Solution (BTLBUW-001) is not indicated for continuous machine perfusion.

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.

K243384: 510(k) Summary

1.0 SUBMITTER

Bridge to Life Ltd
707 Skokie Blvd, Ste. 340 Northbrook, IL 60062

Contact Person	:	Mark Harper
Phone	:	847-796-3070
Fax	:	803-753-9798
Email	:	m.harper@b2ll.com
Date Prepared	:	October 30th, 2024

2.0 DEVICE

Common Name	:	Organ Cold Storage Solution
Proprietary Name	:	Belzer UW® Cold Storage Solution (BTLBUW-001)
Classification Name	:	Isolated kidney perfusion and transport system and accessories
Device Classification	:	Class II, 876.5880
Product Code	:	KDN, KDL

3.0 PREDICATE DEVICE

Company	Device	K Number	Date Cleared
Preservation Solutions, Inc	CoStorSol® Solution	K091245	June 17, 2009

4.0 DEVICE DESCRIPTION

Belzer UW® Cold Storage Solution (BTLBUW-001) is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolarity of 320 mosmol/kg, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

The solution should be used only by medical healthcare staff, adequately trained according to established operating protocols.

The Belzer UW® Cold Storage Solution (BTLBUW-001) is supplied in non-PVC bags: 500 mL bags, shelf carton of 6; 1000 mL in 1-liter bags, shelf carton of 10; and 2000 mL in 2-liter bags, shelf carton of 5. The solution is sterile and is intended for one single use.

The solution should be stored indoors at temperatures controlled between 2° and 25°C (36° and 77°F) until use. Excessive heat and freezing should be avoided. Belzer UW® Cold Storage Solution (BTLBUW-001) should not be used if discolored or if obvious particulate matter, precipitates, or contamination are evident in the solution.

Bridge to Life's Belzer UW® Cold Storage Solution (BTLBUW-001) is substantially

equivalent in composition, safety and efficacy to currently marketed CoStorSol® Solution, which was cleared by the US FDA in prior 510(k) submission **K091245**

Table 1 provides information about the composition of Bridge to Life's Belzer UW® Cold Storage Solution (BTLBUW-001).

Table 1: Composition of Bridge to Life's Belzer UW® Cold Storage Solution (BTLBUW-001)

Component	g/L	Mmol/L
Pentafraction	50	N/A
Lactobionic Acid (as Lactone)	35.83	105
Potassium Phosphate monobasic	3.4	25
Magnesium Sulfate heptahydrate	1.23	5
Raffinose pentahydrate	17.83	30
Adenosine	1.34	5
Allopurinol	0.136	1
Total Glutathione	0.922	3
Potassium Hydroxide	5.61	100
Sodium Hydroxide, 5N	5.0mL/L	25
Water for Injection	q.s.	

5.0 INDICATION FOR USE

Bridge to Life's Belzer UW® Cold Storage Solution (BTLBUW-001) is indicated 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. Belzer UW® Cold Storage Solution (BTLBUW-001) is not indicated for continuous machine perfusion.

6.0 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

	Subject Device	Predicate Device	Comparison
Device	**BTL's Belzer UW® Cold Storage Solution (BTLBUW-001)**	**CoStorSol® Solution**	
510k Number	**K243384**	**K091245**	
Manufacturer	Bridge to Life 707 Skokie Blvd, Ste. 340 Northbrook, IL 60062	Preservation Solutions, Inc., 980 Proctor Drive, Elkhorn, Wisconsin 32121	
Classification & Product Code	876.5880; KDN, KDL	876.5880; KDN	Same

Device Regulation Description	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories	Same
Common Name	Organ Storage Solution	Organ Storage Solution	Same
DESCRIPTION, INDICATIONS, & INTENDED USE			
Device Description	BTL's Belzer UW® Cold Storage Solution (BTLBUW-001) is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolarity of 320 mosmol/kg, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C. The solution is packaged in 500-mL, 1-L and 2-L bags.	CoStorSol® is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolarity of 320 mosmol/kg, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C. The solution is packaged in 1-Liter bags	Same Subject and predicate devices are both used as organ preservation solutions. Devices are used in the organ procurement and transplant process per standard organ preservation practices.
Indications for Use	Belzer UW® Cold Storage Solution (BTLBUW-001) is indicated 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. Belzer UW® Cold Storage Solution (BTLBUW-001) is not indicated for continuous machine perfusion.	CoStorSol® indicated 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 Subject and predicate devices are both used as organ preservation solutions. All devices are used at cold temperatures, to slow biological deterioration in organs removed from their physiological environment per standard organ preservation practices.
Intended Use	Belzer UW® Cold Storage Solution (BTLBUW-001) 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.	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

TECNOLOGICAL CHARACTERISTICS			
Storage Temperature	2º to 25º C	2º to 25º C	Same
Pre-Cooling	Pre-cool solution prior to use (2º to 6º C)	Pre-cool solution prior to use (2º to 6º C)	Same
Maintain Cold Organ Temperature During Storage and Transport	Directly cools the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the patient.	Directly cools the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the patient.	Same
Product State	Liquid – Solution	Liquid - Solution	Same
Composition	50 g/L Pentafraction 35.83 g/L Lactobionic Acid (as Lactone) 3.4 g/L Potassium Phosphate monobasic 1.23 g/L Magnesium Sulfate heptahydrate 17.83 g/L Raffinose pentahydrate 1.34 g/L Adenosine 0.136 g/L Allopurinol 0.922 g/L Total Glutathione 5.61 g/L Potassium Hydroxide 5.0 mL/L Sodium Hydroxide, 5N Water for Injection q.s.	50 g/L Pentafraction 35.83 g/L Lactobionic Acid (as Lactone) 3.4 g/L Potassium Phosphate monobasic 1.23 g/L Magnesium Sulfate heptahydrate 17.83 g/L Raffinose pentahydrate 1.34 g/L Adenosine 0.136 g/L Allopurinol 0.922 g/L Total Glutathione 5.61 g/L Potassium Hydroxide 5.0 mL/L Sodium Hydroxide, 5N Water for Injection q.s.	Same
Osmolality	320 mOsmol/kg	320 mOsmol/kg	Same
pH	Approximately 7.4 at 20ºC	Approximately 7.4 at 20ºC	Same
Fluid Volume	500 ml 1,000 ml 2,000 ml	1,000 ml	Equivalent Subject device has more available size options than the predicate device.
Single Use Only	Yes	Yes	Same

Primary Container	Constructed from Ethylene Vinyl Acetate (EVA). The film is flexible, clear and durable. The container bags are Latex-Free, PVC-Free and DEHP-Free. Sterile, non-pyrogenic fluid path.	Constructed from Ethylene Vinyl Acetate (EVA). The film is flexible, clear and durable. The container bags are Latex-Free, PVC-Free and DEHP-Free. Sterile, non-pyrogenic fluid path.	Equivalent
Protecting Overwrap Bag	Yes	Yes	Same
Shelf Life	6 Months	24 Months	Same. Shelf life stability study is on-going to claim 24 months shelf life.
SAFETY			
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic	Same
Sterility	Sterility assured via 0.2 µm and two 0.1 µm membrane filtration	Sterility assured via 0.1 µ membrane filtration	Same
Sterilization	Aseptic Fill	Aseptic Fill	Same
Biocompatibility	Biocompatible in accordance with ISO 10993-1/2/5/10/12.	Biocompatible in accordance with ISO 10993-1/2/5/10/12.	Equivalent
Sterile Dispensing/ Administration	Fluid is dispensed via sterile port on bag.	Fluid is dispensed via sterile port on bag.	Same
Bag Connections	Fluid delivery and drug administration ports	Fluid delivery and drug administration ports	Same

7.0 NON-CLINICAL PERFORMANCE DATA

Performance data is provided in support of the substantial equivalence determination. All tests performed are included in this submission.

7.1. Biocompatibility

Belzer UW® Cold Storage Solution (BTLBUW-001) has been demonstrated as substantially equivalent in biocompatibility to the predicate device via testing and biological risk assessment, such that it is safe for its intended use.

7.2 Sterilization

Belzer UW® Cold Storage Solution (BTLBUW-001) is aseptically filled and sterility assured via 0.2 µm and two 0.1 µm membrane filtration.

7.3 Shelf Life

Belzer UW® Cold Storage Solution (BTLBUW-001) has a shelf life of 6 months.

8.0 DESIGN CONTROL SUMMARY

All procedural Design Controls were followed, and all design control elements were satisfied.

9.0 SUMMARY OF VERIFICATION & VALIDATION

Verification and validation testing was done on the Belzer UW® Cold Storage Solution (BTLBUW-001). The subject device is substantially equivalent to the predicate device. Any risks to the overall system were addressed in the Risk Analysis. Concerns or risks identified were mitigated by the actual proper use and function Belzer UW® Cold Storage Solution (BTLBUW-001) indicated in the Instructions for Use. It is appropriate to conclude that Belzer UW® Cold Storage Solution (BTLBUW-001) is substantially equivalent to the predicate device **K091245**.

10.0 CONCLUSION

The subject and predicate devices have the same intended use and are substantially equivalent in technological characteristics and performance (same composition). The Belzer UW® Cold Storage Solution (BTLBUW-001) is safe and effective as the predicate device. The non-clinical data supports and demonstrates the safety of the device.

The conclusion is that Belzer UW® Cold Storage Solution (BTLBUW-001) is substantially equivalent to the legally marketed CoStorSol® Solution and therefore should have clearance for premarket activities in the United States.