March 26, 2025

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

Re: K243840
Trade/Device Name: Belzer MPS® (UW Machine Perfusion Solution) (BMPS-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: December 13, 2024
Received: February 24, 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,

Maura Rooney -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)*
K243840

Device Name
Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001)

Indications for Use *(Describe)*
Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is indicated for the in vitro flushing and continuous hypothermic machine perfusion of explanted abdominal organs.

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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K243840: 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	:	December 13th 2024

2.0 DEVICE

Proprietary Name	:	Belzer MPS® (UW Machine Perfusion Solution) (BMPS-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	MaPerSol® Solution	K080432	August 8, 2008

4.0 DEVICE DESCRIPTION

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is a clear to straw-colored, sterile, non-pyrogenic solution for the in-vitro flushing and continuous perfusion of explanted abdominal organs. The Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) has the same composition and indication for use as MaPerSol® Organ Preservation Solution.

The solution is consistent with an extracellular solution, based on its sodium/potassium ratio and has a calculated potassium concentration of 25 mEq/L, a sodium concentration of 100 mEq/L, an osmolarity of 300 mosmol/kg, and a pH of approximately 7.4 at 20°C.

The Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is supplied in single use 1000mL solution bags, made from flexible PVC free material (e.g., laminated EVA film) with at least two integrated ports including ports for delivery and component addition. Each individual bag is enclosed in a protective outer overwrap bag. The solution is sterile and is intended for one single use.

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

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 MPS® (UW Machine Perfusion Solution) (BMPS-001) should not be used if discolored or if obvious particulate matter, precipitates, or contamination are evident in the solution.

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is substantially equivalent in composition, safety and efficacy to currently marketed MaPerSol® Solution, which was cleared by the US FDA in prior 510(k) submission K080432.

Table 1 provides information about the composition of Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001).

Table 1: Composition of Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001)

Component	g/L	Mmol/L
Adenine (free base)	0.68g	5
Calcium Chloride (dihydrate)	0.068g	0.5
Dextrose (+)	1.80g	10
Glutathione (reduced)	0.92g	3
HEPES (free acid)	2.38 g	10
Hydroxyethyl Starch	50.0g	**N/A**
Magnesium Gluconate	1.13 g	5
Mannitol	5.4 g	30
Potassium Phosphate (monobasic)	3.4 g	25
Ribose, D(-)	0.75g	5
Sodium Gluconate	17.45 g	80
Sodium Hydroxide	0.70g	**N/A**
Sterile Water	To 1000 ml Volume	

5.0 INDICATION FOR USE

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is indicated for the *in-vitro* flushing and continuous hypothermic machine perfusion of explanted abdominal organs.

6.0 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

	Subject Device	Predicate Device	Reference Device	Comparison
Device	Belzer MPS® (UW Machine Perfusion Solution (BMPS-001)	MaPerSol® Organ Preservation Solution (UW Machine Perfusion Solution)	EasiSlush® Cold Storage Solution	
510k Number	K243840	K080432	K191006	

Manufacturer	Bridge to Life 707 Skokie Boulevard Suite 340, Northbrook, IL 60062	Preservation Solutions, Inc., 980 Proctor Drive, Elkhorn, Wisconsin 53121	Bridge to Life 707 Skokie Boulevard Suite 340, Northbrook, IL 60062	-
Classification & Product Code	876.5880; KDN	876.5880; KDN	876.5880; KDN	Same
Device Regulation Description	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
Common Name	Organ Preservation Solution	Organ Preservation Solution	0.9% Saline Slush Solution	Same
DESCRIPTION, INDICATIONS, & INTENDED USE				
Device Description	BTL's Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is a clear to straw-colored solution for the *in-vitro* flushing and continuous machine perfusion of explanted abdominal organs. This solution is consistent with an extracellular solution, based on its sodium/potassium ratio. This solution has a calculated potassium concentration of 25 mEq/L, a sodium concentration of 100 mEq/L, an osmolarity of 300 mosmol/kg, and a pH of approximately 7.4 at 20°C. The solution is packaged in 1-L bags.	MaPerSol® Organ Preservation Solution is a clear to straw-colored solution for the *in-vitro* flushing and temporary continuous perfusion preservation of explanted kidneys. This solution is consistent with an extracellular solution, based on its sodium/potassium ratio. This solution has a calculated potassium concentration of 25 mEq/L, a sodium concentration of 100 mEq/L, an osmolarity of 300 mosmol/kg, and a pH of approximately 7.4 at 20°C. The solution is packaged in 1-Liter bags	EasiSlush® is a clear, colorless 0.9% Sodium Chloride solution for preparation of slushed solution to provide hypothermia during the recovery, storage, and transport of donor organs for transplantation. The solution is sterile, non-pyrogenic, isotonic and is contained in a 2L sterile, flexible, non- PVC bag.	Same Subject, predicate and reference devices are all used as organ preservation solutions. Devices are used in the organ procurement and transplant process per standard organ preservation practices.
Indications for Use	Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is indicated for the *in-vitro* flushing and continuous hypothermic machine perfusion of explanted abdominal organs.	MaPerSol® Organ Preservation Solution is indicated for in vitro flushing and continuous hypothermic machine perfusion of explanted kidneys.	EasiSlush slushed solution is intended for topical cooling of in-situ, abdominal donor organs during intraoperative recovery from the donor. It is also intended to maintain organ hypothermia during storage and transport to the transplant recipient. EasiSlush™ slushed solution is used to establish, and maintain hypothermia of donor organs during recovery, storage, and	Same Subject, predicate and reference devices are all used as organ preservation solutions. All devices are used at cold hypothermic temperatures, to slow biological deterioration in organs removed from their physiological environment per standard organ preservation practices. Specifically: Use #1 – Similar.

			transport. [….]	Subject device is similar to the predicate device in which they are both intended to flush, perfuse, or be left in the abdominal organ. Use #2 - Similar During organ perfusion, subject and predicate device create hypothermia, by cooling of organ. Use #3 - Similar Subject device is similar to the reference device in which both are used for organ preservation solution by maintaining organ hypothermia, by cooling the organ during preservation.
Intended Use	Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is intended for *in- vitro* flushing and continuous hypothermic machine perfusion of explanted abdominal organs.	MaPerSol® Organ Preservation Solution is intended for the *in-vitro* flushing and continuous hypothermic machine perfusion preservation of explanted kidneys.	EasiSlush™ slushed solution is intended for topical cooling of in- situ, abdominal donor organs during intraoperative recovery from the donor. It is also intended to maintain organ hypothermia during storage and transport to the transplant recipient.	Similar Subject device is an accessory to organ preservation solutions. All devices are intended for use at cold hypothermia, to slow biological deterioration in organs removed from their physiological environment per standard organ preservation practices.
TECNOLOGICAL CHARACTERISTICS				
Storage Temperature	2º to 25º C	2º to 25º C	2º to 25º C	Same
Pre-Cooling	Pre-cool solution prior to use (2º to 8º C)	Pre-cool solution prior to use (2º to 8º C)	Pre-cool solution prior to use (-4 º to -15 º C)	Similar Subject, predicate and reference solutions are all pre-cooled to hypothermic temperature ranges
In-Situ Organ Cooling	Internal cooling of organ from perfusion of cold solution through organ blood vessels	Internal cooling of organ from perfusion of cold solution through organ blood vessels	External and internal cooling of organ	Same Subject, predicate and reference device are all for internal cooling of organ from perfusion of cold solution through organ blood vessels.
Maintain Cold Organ Temperature During Storage and Transport	Directly cools organ external and internal surfaces via contact with cold solution.	Directly cools organ external and internal surfaces via contact with cold solution.	Directly cools the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the patient.	Same Overall system performance by cooling/maintaining hypothermic temperature

				of organs are similar for all devices.
Product State	Liquid – Solution	Liquid - Solution	Liquid - Solution	Same
Composition	Adenine (free base) 0.68 g/L Calcium Chloride (dihydrate) 0.068 g/L Dextrose (+) 1.80 g/L Glutathione (reduced) 0.92 g/L HEPES (free acid) 2.38 g/L Hydroxyethyl Starch 50.0 g/L Magnesium Gluconate 1.13 g/L Mannitol 5.4 g/L Potassium Phosphate (monobasic) 3.4 g/L Ribose, D(-) 0.75 g/L Sodium Gluconate 17.45 g/L Sodium Hydroxide 0.70 g/L Sterile Water for Injection To 1000 mL Volume	Adenine (free base) 0.68 g/L Calcium Chloride (dihydrate) 0.068 g/L Dextrose (+) 1.80 g/L Glutathione (reduced) 0.92 g/L HEPES (free acid) 2.38 g/L Hydroxyethyl Starch 50.0 g/L Magnesium Gluconate 1.13 g/L Mannitol 5.4 g/L Potassium Phosphate (monobasic) 3.4 g/L Ribose, D(-) 0.75 g/L Sodium Gluconate 17.45 g/L Sodium Hydroxide 0.70 g/L Sterile Water for Injection To 1000 mL Volume	Buffered saline solution. 0.9% Sodium Chloride Irrigation USP	Same Subject and predicate devices are of the same exact chemical composition.
Osmolality	300 mOsmol/kg	300 mOsmol/kg	300 mOsmol/kg	Same
pH	Approximately 7.4 at 20ºC	Approximately 7.4 at 20ºC	4.5–7.0 (per USP monograph for 0.9% Sodium Chloride Irrigation)	Same Subject and predicate devices have the same pH specifications
Fluid Volume	1,000 ml	1,000 ml	1,250ml	Same Subject device is available in same volume as the predicate device.
Single Use Only	Yes	Yes	Yes	Same
Primary Container	PVC-Free Bag	PVC-Free Bag	PVC-Free Bag	Equivalent
Protecting Overwrap Bag	Yes	Yes	Yes	Same
Shelf Life	6 Months	24 Months	24 Months	Same. Shelf life stability study is on-going to meet 24 months shelf life.
SAFETY				

Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic	Non-Pyrogenic	Same
Sterility	Sterility assured via 0.2 µ and two 0.1 µ membrane filtrations	Sterility assured via 0.1 µ membrane filtration	Terminally sterilized	Same
Sterilization	Aseptic processing and sterile filtration	Aseptic processing and sterile filtration	Terminal gamma irradiation	Same All devices are sterile.
Biocompatibility	Biocompatible in accordance with ISO 10993-1/2/5/10/12.	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.	Sterile bag is cut with sterile instrument and contents dispensed to desired location.	Similar
Bag Connections	Fluid port provided for organ flushing	Fluid port provided for organ flushing	None	Same Subject and predicate device are same. Different Reference device is not intended for organ flushing, so no port is provided.

7.0 NON-CLINICAL PERFORMANCE DATA

7.1. Biocompatibility

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-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 Sterility

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is aseptically filled and sterility assured via 0.2 µ and two 0.1 µ membrane filtration.

7.3 Shelf Life

Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) has a shelf life claim 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 MPS® (UW Machine Perfusion Solution) (BMPS-001). The subject device is substantially equivalent to the predicate and reference 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 MPS® (UW Machine Perfusion Solution) (BMPS-001) indicated in the Instructions for Use. It is appropriate to conclude that Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is substantially equivalent to the predicate device K080432.

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 MPS® (UW Machine Perfusion Solution) (BMPS-001) is safe and effective as predicate and reference devices. The non-clinical data supports and demonstrates the safety of the device.

The conclusion is that Belzer MPS® (UW Machine Perfusion Solution) (BMPS-001) is substantially equivalent to the legally marketed MaPerSol® Solution and therefore should have clearance for premarket activities in the United States.