June 17, 2025

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

Re: K243618
Trade/Device Name: EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250)
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories
Regulatory Class: Class II
Product Code: KDN
Dated: May 16, 2025
Received: May 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,

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)*
K243618

Device Name
EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250)

Indications for Use *(Describe)*
EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) 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® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is used to establish, and maintain hypothermia of donor organs during recovery, storage, and transport.

It is also indicated for use during open surgical procedures such as cardiovascular, abdominal, and transplant surgeries.

Organ Recovery
Prior to organ recovery, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is delivered to the open peritoneal cavity of the donor to assist in creating hypothermia by topically cooling external surfaces of organs for recovery. During organ recovery, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established transplant team procedures. (Temperature rise may be assessed with temperature probes, being careful that the probe is measuring the solution and is not in contact with the organ).

Organ Storage/Transport
For organ storage/transport, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) may be used to topically cool external surfaces of a sterile, sealed, primary organ bag containing chilled preservation solution and the organ. In this application, the slushed solution may be added to a secondary bag or to a tertiary hard container to surround the primary organ bag. Once bagged, the organ can be placed in a bed of non-sterile ice in an insulated transport container, which is then closed. Actual use should follow standard practices of the OPO or hospital for transporting and storing specific types of donor organs using sterile, slush solutions.

Surgical Procedure
During surgical procedures, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is delivered to assist in creating hypothermia by topically cooling external surfaces of organs. During the procedure, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established surgical team procedures.

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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K243618: 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: November 22nd, 2024

2.0 DEVICE

Proprietary Name : EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250)
Common Name : EasiSlush® Slush Solution
Classification Name : Isolated kidney perfusion and transport system and accessories
Device Classification : Class II, 876.5880
Product Code : KDN

3.0 PREDICATE DEVICE

Company	Device	K Number	Date Cleared
Bridge to Life	EasiSlush®	K191006	Sept. 24, 2019

4.0 DEVICE DESCRIPTION

EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) 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 and to induce regional hypothermia in certain surgical procedures such as open heart and kidney procedures by direct application of slushed solution. The solution is sterile, non-pyrogenic, isotonic and is contained in a 2L sterile, flexible, non- PVC bag.

5.0 INTENDED USE

EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is intended for *in* situ topical cooling during surgical procedures and during intraoperative recovery from an organ transplant donor. It is also intended to maintain organ hypothermia during storage and transport to the transplant recipient.

6.0 INDICATIONS FOR USE

EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) 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® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is used to establish, and maintain hypothermia of donor organs during recovery, storage, and transport.

It is also indicated for use during open surgical procedures such as cardiovascular, abdominal, and transplant surgeries.

Organ Recovery

Prior to organ recovery, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is delivered to the open peritoneal cavity of the donor to assist in creating hypothermia by topically cooling external surfaces of organs for recovery. During organ recovery, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established transplant team procedures. (Temperature rise may be assessed with temperature probes, being careful that the probe is measuring the solution and is not in contact with the organ).

Organ Storage/Transport

For organ storage/transport, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) may be used to topically cool external surfaces of a sterile, sealed, primary organ bag containing chilled preservation solution and the organ. In this application, the slushed solution may be added to a secondary bag or to a tertiary hard container to surround the primary organ bag. Once bagged, the organ can be placed in a bed of non-sterile ice in an insulated transport container, which is then closed. Actual use should follow standard practices of the OPO or hospital for transporting and storing specific types of donor organs using sterile, slush solutions.

Surgical Procedure

During surgical procedures, EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation (BTLE-1250) is delivered to assist in creating hypothermia by topically cooling external surfaces of organs. During the procedure, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established surgical team procedures.

7.0 SUBSTANTIAL EQUIVALENCE DISCUSSION

7.1 Historical 510(k) Clearance

EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is a clear, colorless, 0.9% Sodium Chloride solution for the preparation of slushed solution. The solution is sterile, non-pyrogenic, isotonic and is contained in a 2L sterile, flexible, non-PVC bag. EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) received 510k clearance in 2019, under K191006, as a Class II medical device for the intended use of establishing and maintaining regional hypothermia of donor organs during recovery, storage, and transport.

7.2 Summary of Key Feature Changes

This 510(k) submission is to expand the EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) Indications for Use for surgical procedures, such as open heart and kidney surgeries, for the same intended use of establishing and maintaining topical hypothermia by direct application of slushed saline. There have been no changes to the technological characteristics from the predicate device to the subject device. There are no changes to the formulation, method of use, packaging, sterilization method, slush preparation, delivery method, or mode of action by which the devices achieve their effects.

To illustrate the substantial equivalence of subject EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) to the predicate EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) cleared in 2019, a high-level comparison is provided in **Table 1**.

Table 1. Comparative Summary of the Subject EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) with the Predicate EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) (cleared under K191006)

Detail and Technological Characteristic	Previously Cleared EasiSlush® (K191006)	Under Review	***Comparison***
Device	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250)	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250)	
510k Number	K191006	K243618	
Manufacturer	Bridge to Life 707 Skokie Boulevard Suite 340, Northbrook, IL 60062	Bridge to Life 707 Skokie Boulevard Suite 340, Northbrook, IL 60062	***No Change***
Classification & Product Code	876.5880; KDN	876.5880; KDN	***No Change***
Device Regulation Description	Isolated kidney perfusion and transport system and accessories	Isolated kidney perfusion and transport system and accessories	***No Change***
Common Name	0.9% Saline Slush Solution	0.9% Saline Slush Solution	***No Change***
DESCRIPTION, INDICATIONS, & INTENDED USE			
Device Description	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) 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.	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) 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 and intraoperatively to provide topical cooling in situ for surgical procedures. The solution is sterile, non-pyrogenic, isotonic and is	***EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) can be used to provide topical cooling in certain surgical procedures such as open heart and kidney procedures by direct application of slushed solution.*** ***There is no change to the***

		contained in a 2L sterile, flexible, non-PVC bag.	***intended purpose of the slushed solution.***
Indications for Use	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) 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® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is used to establish, and maintain hypothermia of donor organs during recovery, storage, and transport. **Organ Recovery** Prior to organ recovery, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is delivered to the open peritoneal cavity of the donor to assist in creating hypothermia by topically cooling external surfaces of organs for recovery. During organ recovery, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional EasiSlush slushed solution may be delivered per established transplant team procedures. (Temperature rise may be assessed with temperature probes, being careful that the probe is measuring the solution and is not in contact with the organ). **Organ Storage/Transport** For organ storage/transport, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) may be used to topically cool external surfaces of a sterile, sealed, primary organ bag containing chilled preservation solution and the organ. In this application,	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) 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® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is used to establish, and maintain hypothermia of donor organs during recovery, storage, and transport. It is also indicated for use during open surgical procedures such as cardiovascular, abdominal, and transplant surgeries. **Organ Recovery** Prior to organ recovery, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is delivered to the open peritoneal cavity of the donor to assist in creating hypothermia by topically cooling external surfaces of organs for recovery. During organ recovery, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established transplant team procedures. (Temperature rise may be assessed with temperature probes, being careful that the probe is measuring the solution and is not in contact with the organ). **Organ Storage/Transport** For organ storage/transport, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) may be	***General Indications for Use Same: EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is used for topical cooling of in situ and donor organs. Device is used at hypothermic temperatures, to slow biological deterioration in organs.*** ***Specifically:*** ***Use #1 – Organ Recovery – Same*** ***Use #2 – Organ Storage/Transport – Same.*** ***Use #3 - Surgical Procedure*** ***During surgical procedures, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is delivered to topically cool the exterior surface of organs to reduce metabolic activity so that tissues can tolerate a period of total or relative ischemia.***

	EasiSlush may be added to a secondary bag or to a tertiary hard container to surround the primary organ bag. Once bagged, the organ can be placed in a bed of non-sterile ice in an insulated transport container, which is then closed. Actual use should follow standard practices of the OPO or hospital for transporting and storing specific types of donor organs using sterile, slush solutions.	used to topically cool external surfaces of a sterile, sealed, primary organ bag containing chilled preservation solution and the organ. In this application, the slushed solution may be added to a secondary bag or to a tertiary hard container to surround the primary organ bag. Once bagged, the organ can be placed in a bed of non-sterile ice in an insulated transport container, which is then closed. Actual use should follow standard practices of the OPO or hospital for transporting and storing specific types of donor organs using sterile, slush solutions. **Surgical Procedure** During surgical procedures, EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is delivered to assist in creating hypothermia by topically cooling external surfaces of organs. During the procedure, if ice crystals are no longer visible, the temperature of the saline solution will begin to rise and additional slushed solution may be delivered per established surgical team procedures.	
Intended Use	EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) 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® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is intended for *in situ* topical cooling during surgical procedures and during intraoperative recovery from an organ transplant donor. It is also intended to maintain organ hypothermia during storage and transport to the transplant recipient.	***Same***
TECNOLOGICAL CHARACTERISTICS			
Storage Temperature	2o to 25o C	2o to 25o C	***No Change***
Pre-Cooling	Pre-cool solution prior to use (-4 o to -15 o C)	Pre-cool solution prior to use (-4 o to -15 o C)	***No Change***
In-Situ Organ	External and internal cooling of	External and internal cooling of	***No Change***

Cooling	organ	organ	
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.	***No Change***
Product State	Liquid - Solution	Liquid - Solution	***No Change***
Composition	Buffered saline solution. 0.9% Sodium Chloride Irrigation USP	Buffered saline solution. 0.9% Sodium Chloride Irrigation USP	***No Change***
Osmolality	300 mOsmol/kg	300 mOsmol/kg	***No Change***
pH	4.5–7.0 (per USP monograph for 0.9% Sodium Chloride Irrigation)	4.5–7.0 (per USP monograph for 0.9% Sodium Chloride Irrigation)	***No Change***
Fluid Volume	1,250ml	1,250ml	***No Change***
Single Use Only	Yes	Yes	***No Change***
Primary Container	PVC-Free Bag	PVC-Free Bag	***No Change***
Protecting Overwrap Bag	Yes	Yes	***No Change***
Shelf Life	24 Months	24 Months	***No Change***
SAFETY			
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic	***No Change***
Sterility	Terminally sterilized	Terminally sterilized	***No Change***
Sterilization	Terminal gamma irradiation	Terminal gamma irradiation	***No Change***
Biocompatibility	Biocompatible in accordance with ISO 10993-1/2/5/10/12.	Biocompatible in accordance with ISO 10993-1/2/5/10/12.	***No Change***
Sterile Dispensing/ Administration	Sterile bag is cut with sterile instrument and contents dispensed to desired location.	Sterile bag is cut with sterile instrument and contents dispensed to desired location.	***No Change***
Bag Connections	None	None	***No Change***

8.0 CONCLUSION

The comparative analysis of the EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) subject device to the predicate EasiSlush® (Sodium Chloride Solution for Sterile Slush

Preparation) (BTLE-1250) device demonstrates that:

- The intended use of the subject device is the same as the predicate.
- The indications for use have been expanded but remain within the scope of the same intended use.
- There are no new technological characteristics.
- The proposed expansion for the indication of use of the subject device does not raise new questions of safety or effectiveness.

Therefore, the subject device meets the requirements for substantial equivalence under 21 CFR 807.100 and the subject EasiSlush® (Sodium Chloride Solution for Sterile Slush Preparation) (BTLE-1250) is as safe and effective for its intended use as the previously cleared 510(k).