September 24, 2019

Bridge to Life Ltd.
℅ Richard O. Wood
Senior Member
The Wood Burditt Group LLC
10 E. Scranton Ave, Ste. 201
Lake Bluff, IL 60044

Re: K191006
Trade/Device Name:  EasiSlush™ (Sodium Chloride Solution for Sterile Slush Preparation)
(0.9% Sodium Chloride Irrigation, USP)
Regulation Number:  21 CFR 876.5880
Regulation Name:  Isolated kidney perfusion and transport system
and accessories
Regulatory Class:  II
Product Code:  KDN
Dated:  August 21, 2019
Received:  August 23, 2019

Dear Richard Wood:

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.


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

for Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastro-Renal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
EasiSlush™ (Sodium Chloride Solution for Sterile Slush Preparation) (0.9% Sodium Chloride Irrigation, USP)

Indications for Use (Describe)

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 transport.

Organ Recovery
Prior to organ recovery, EasiSlush™ slushed solution 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™ slushed solution 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 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.

Type of Use (Select one or both, as applicable)

- [x] 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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5. 510(k) Summary

Bridge to Life EasiSlush™
(sodium chloride solution for sterile slush preparation)

Submitter Information:
Bridge to Life Ltd.
128 Suber Rd. Suite A
Columbia, SC 29210
Contact Person: Richard O. Wood, the Wood Burditt Group
Phone: (847) 234-7500 x 203
Fax: (847) 574-0728
Email: rowood@woodburditt.com
Date Prepared: September 13, 2019

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

Predicate Devices:

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>K Number</th>
<th>Predicate Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preservation Solutions Inc.</td>
<td>CoStorSol®</td>
<td>K073693</td>
<td>Primary</td>
</tr>
<tr>
<td>Preservation Solutions Inc.</td>
<td>MaPerSol®</td>
<td>K080432</td>
<td>Reference</td>
</tr>
</tbody>
</table>

Description of Device:
EasiSlush (Sodium Chloride Solution for Sterile Slush Preparation) is 1.25L sterile 0.9% Sodium Chloride Solution in a 2L bag. It meets the USP 34 monograph for Sodium Chloride Irrigation. It is a sterile, nonpyrogenic, isotonic solution that is chilled for the preparation of slushed solution.

Indication for Use:
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 transport.

Organ Recovery
Prior to organ recovery, EasiSlush™ slushed solution 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™ slushed solution 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 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.
Technological Characteristics and Comparison

For its Intended Uses, EasiSlush™ slushed solution is substantially equivalent to both the Predicate and Reference preservation solutions and the subset of their intended uses to create hypothermia during organ recovery, storage, and transport to slow biological deterioration in organs to be removed from their physiological environment per standard organ preservation practices. Both the Predicate and Reference Devices are also intended for use to flush, perfuse and/or remain in the organ after retrieval. Such intended uses are not claimed for EasiSlush.

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

<table>
<thead>
<tr>
<th>Device Description</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Reference Device</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EasiSlush™</strong> 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.</td>
<td><strong>CoStorSol®</strong> is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution is packaged in 1-liter bags, which must be chilled to between 2° and 6°C prior to use. The solution may be used without any point of use filtration.</td>
<td><strong>MaPerSol®</strong> is a colorless, sterile, non-pyrogenic, non-toxic solution for in-vitro flushing and continuous perfusion of explanted kidneys. The solution is packaged in 1-liter bags.</td>
<td>Similar</td>
<td></td>
</tr>
<tr>
<td><strong>Device Classification &amp; Product Code</strong></td>
<td>876.5880; KDN</td>
<td>876.5880; KDN</td>
<td>876.5880; KDN</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Device Manufacturer</strong></td>
<td>Intermountain Life Sciences, UT, USA</td>
<td>Preservation Solutions Inc., WI, USA</td>
<td>Preservation Solutions Inc., WI, USA</td>
<td>-</td>
</tr>
<tr>
<td><strong>Common Name</strong></td>
<td>0.9% Saline Slush Solution</td>
<td>Organ Storage Solution</td>
<td>Organ Preservation Solution</td>
<td>-</td>
</tr>
<tr>
<td><strong>510k Number</strong></td>
<td>K191006</td>
<td>K073693</td>
<td>K080432</td>
<td></td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Organ Recovery</td>
<td>Belzer UW® Cold Storage Solution</td>
<td>Pre-cool the kidney by vascular flush-out using Belzer MPS® or other cooled solutions (2°-8°C) (Belzer UW® Cold Storage Solution, Ringers, or saline). The kidney should be perfused following the manufacturer’s or perfusion center’s protocol.</td>
<td>Similar</td>
</tr>
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</tr>
<tr>
<td>Prior to organ recovery, EasiSlush™ slushed solution 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).</td>
<td>Belzer UW® Cold Storage Solution must be cooled to 2° to 6°C (36° to 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. Belzer UW® Cold Storage Solution is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion.</td>
<td>Subject device is an accessory to organ preservation solutions. All devices are used at cold temperatures, per standard preservation practices, to slow biological deterioration in organs removed from their physiological environment. Specifically: Use #1 – Similar. During organ retrieval, subject device augments predicate to create hypothermia, by topical/external cooling of organ. Use #2 - Similar. During storage and transport, subject device augments predicate in maintaining organ hypothermia, by cooling the organ and preservation solution, which are sealed in a medical-grade bag. Use #3 – Different. Not Applicable. Subject device is not intended to flush, perfuse, or be left in the organ.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organ Storage/Transport</td>
<td>For organ storage/transport, EasiSlush™ slushed solution 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 may be added to a secondary bag or to</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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.

### Intended Use

**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.

**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.

**MaPerSol®** organ preservation solution is intended for in-vitro flushing and continuous hypothermic perfusion of explanted kidneys.

Subject device is an accessory to organ preservation solutions. All devices are intended for use at cold temperatures, to slow biological deterioration in organs removed from their physiological environment per standard organ preservation practices.

<table>
<thead>
<tr>
<th>TECNOLOGICAL CHARACTERISTICS</th>
<th>EasiSlush™</th>
<th>CoStorSol®</th>
<th>MaPerSol®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage Temperature</strong></td>
<td>2°C to 25°C</td>
<td>2°C to 25°C</td>
<td>2°C to 25°C</td>
</tr>
<tr>
<td><strong>Pre-Cooling</strong></td>
<td>Pre-cool solution prior to use (-4°C to -15°C)</td>
<td>Pre-cool solution prior to use (2°C to 6°C)</td>
<td>Pre-cool solution prior to use (2°C to 8°C)</td>
</tr>
<tr>
<td><strong>In-Situ Organ Cooling</strong></td>
<td>Topical cooling of external organ surfaces from direct contact with subject device.</td>
<td>Internal cooling of organ by perfusion of cold solution through organ blood vessels</td>
<td>Internal cooling of organ from perfusion of cold solution through organ blood vessels</td>
</tr>
<tr>
<td><strong>Similar</strong></td>
<td>Subject solution is used as “slush” (mixture of ice and liquid), while predicate is used as a very cold liquid</td>
<td></td>
<td>Subject device is complementary and augments performance of predicate for intended use.</td>
</tr>
</tbody>
</table>
| Maintain Cold Organ Temperature During Storage and Transport | Indirectly maintains cold organ temperature by contact with, and cooling of, the outer surface of a sealed container which contains preservation solution and the organ. | Directly cools organ external and internal surfaces via contact with cold solution. | Directly cools organ external and internal surfaces via contact with cold solution. | Similar
Subject device augments overall system performance by cooling/maintaining temperature of predicate device and the organ. |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product State</td>
<td>Liquid – Solution</td>
<td>Liquid - Solution</td>
<td>Liquid - Solution</td>
<td>Same</td>
</tr>
</tbody>
</table>
| Composition                                                | Buffered saline solution, 0.9% Sodium Chloride Irrigation USP                                  | Saline solution with additive salt and organic compounds.                                     | Saline solution with additive salt and organic compounds.                                     | Different
Not Applicable
Subject device does not include additive chemicals for organ preservation. |
| Osmolality                                                  | 308 mOsm (calc)                                                                                | 320 mOsm                                                                                        | 300 mOsm                                                                                        | Similar                                                                                         |
| pH                                                         | 4.5–7.0 (per USP monograph for 0.9% Sodium Chloride Irrigation)                                | 7.2-7.6                                                                                         | 7.2-7.6                                                                                         | Similar
<p>| Fluid Volume                                                | 1,250 ml                                                                                       | 1,000 ml                                                                                       | 1,000 ml                                                                                       | Similar                                                                                         |
| Single Use Only                                            | Yes                                                                                            | Yes                                                                                            | Yes                                                                                            | Same                                                                                             |
| Primary Container                                          | PVC-Free Bag                                                                                  | PVC-Free Bag                                                                                  | PVC-Free Bag                                                                                  | Same                                                                                             |
| Secondary Overwrap Pouch(es)                               | Sterile barrier pouch (Tyvek®-poly) PLUS Dust cover pouch (poly)                               | Dust cover pouch (poly)                                                                        | Dust cover pouch (poly)                                                                        | Similar                                                                                         |
| Shelf Life                                                 | 12 Months Initially; extended to 24 Months based on successful execution of stability protocol. | 24 Months                                                                                     | 24 Months                                                                                     | Same                                                                                             |</p>
<table>
<thead>
<tr>
<th>SAFETY</th>
<th>Pyrogenicity</th>
<th>Sterility</th>
<th>Sterilization</th>
<th>Biocompatibility</th>
<th>Sterile Dispensing/Administration</th>
<th>Bag Connections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-Pyrogenic</td>
<td>Sterile solution. Sterile exterior surface of bag.</td>
<td>Terminal gamma irradiation</td>
<td>Biocompatible per testing to ISO 10993-1</td>
<td>Sterile bag is cut with sterile instrument and contents dispensed to desired location</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Non-Pyrogenic</td>
<td>Sterile solution</td>
<td>Aseptic processing and sterile filtration</td>
<td>Biocompatible per testing to ISO 10993-1</td>
<td>Fluid is dispensed via sterile port on bag.</td>
<td>Fluid port provided for organ flushing</td>
</tr>
<tr>
<td></td>
<td>Non-Pyrogenic</td>
<td>Sterile solution</td>
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</tr>
<tr>
<td></td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
<td>Similar</td>
<td>Different</td>
</tr>
</tbody>
</table>

**Substantial Equivalence Discussion**

In the comparison above, it is shown that the predicate and reference organ preservation solutions provide two principal benefits: 1) they are formulated to maintain the intracellular electrolyte balance of the organ; and 2) they are delivered chilled to rapidly create hypothermia in the organ during recovery, storage and transport. Substantial equivalence of EasiSlush to the predicate solution is based solely on the use of EasiSlush to create hypothermia during recovery, storage and transport, which hypothermia is long-standing and universally accepted goal in organ transplant. The differences between the subject device and predicate and reference devices related to hypothermia creation do not raise issues of safety and effectiveness.

**Performance Data**

**Non-Clinical Performance Testing**

Biocompatibility: A biocompatibility assessment was completed successfully according to ISO 10993 and the FDA guidance document titled “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.’"

- **Cytotoxicity** Based on the criteria of the protocol of ISO 10993-5
- **Sensitization** Based on the criteria of the protocol of ISO 10993-10
- **Irritation – IC Reactivity** Based on the criteria of the protocol of ISO 10993-10
Systemic Toxicity – Acute Based on the criteria of the protocol of ISO 10993-11
Hemocompatibility – Hemolysis Based on the criteria of the protocol of ISO 10993-4
USP Rabbit Pyrogen Based on the criteria of the protocol of ISO 10993-11

Conclusion: EasiSlush satisfies the applicable biocompatibility assessments.

Leachables: Studies were completed to determine the leachable amounts of chemical compounds from the EasiSlush bag system, which included a determination of:

- **Volatile Organic Compounds (VOC)** by GC/MS
- **Semi-Volatile Organic Compounds (SVOC)** by Solvent Extraction GC/MS
- **Target Non-Volatile Organic Compounds (NVOC)** and **Organic Acids** by LC/MS
- **Non-Target NVOC** by LC/UV-Vis

Conclusion: The leachables identified are not toxicologically significant.

Sterility: EasiSlush, including the exterior surfaces of the solution bag and the interior surfaces of the sterile barrier pouch, are terminally sterilized to Sterility Assurance Level (SAL) $10^{-6}$ by gamma irradiation. The irradiation sterilization dose range was established by completion of the AAMI/ISO validation dose setting protocol as described in ANSI/AAMI/ISO 11137-2.

Conclusion: The device is provided sterile.

Performance Bench Tests:

**Temperature**: Bench tests were performed to demonstrate that the temperature of EasiSlush, when prepared per the Directions for Use, was at or above the temperature at which the exterior of an organ might freeze, and when in contact with a simulated organ, that simulated organ did not near a freezing temperature.

**Temperature**: Bench tests were performed to demonstrate a worst case in which EasiSlush, at about -15°C, delivered to a simulated organ did not cause the exposed organ surfaces to reach a freezing temperature.

**Temperature**: Bench test were performed to measure the temperature of EasiSlush prepared according to the Instructions for Use. These tests demonstrated that the temperature of EasiSlush at the time of delivery were higher than the temperature that would present a freezing risk to the external surfaces of organs.

**Temperature in Storage/Transport Container**: Bench tests were performed to measure the temperature of EasiSlush when it was used in a secondary container surrounding the sterile, sealed, primary organ bag containing chilled preservation solution and the organ. The organ was then placed in a cooler with frozen non-sterile crushed ice. Hypothermic temperature of the EasiSlush was maintained for over 36 hours.

Conclusion: The studies demonstrated that the temperatures were appropriate to provide the rapid organ cooling desired without risk of freezing the surface of the organ.

United States Pharmacopeia:

EasiSlush meets the monograph for Sodium Chloride Irrigation.

Finally, a risk analysis on the proposed device in accordance with ISO 14971:2007 was conducted. By considering the issues raised in the FDA guidance document on the subject, all identified risks have been addressed through device design, verification/validation or through documentation (labeling and Instructions for Use) provided to the user.

Clinical Performance Testing

No clinical testing has been performed on this device.
Conclusion on Substantial Equivalence: Substantial equivalence of EasiSlush to the predicate solution is based solely on the use of EasiSlush to create hypothermia during recovery, storage and transport, which hypothermia is long-standing and universally accepted goal in organ transplant. The differences between the subject device and predicate and reference devices related to hypothermia creation do not raise issues of safety and effectiveness.