July 1, 2021

Bridge to Life Ltd.
% H. Carl Jenkins
Regulatory Affairs Counsel
Wood Burditt Group
10 E. Scranton Ave., Ste. 201
Lake Bluff, IL 60044

Re: K203262
Trade/Device Name: Cannula for Organ Perfusion
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated Kidney Perfusion and Transport System and Accessories
Regulatory Class: II
Product Code: KDN, MSB
Dated: May 27, 2021
Received: May 28, 2021

Dear H. Carl Jenkins:

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,

Carolyn Y. Neuland, Ph.D.
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)*
K203262

Device Name

Cannula for Organ Perfusion

Indications for Use *(Describe)*

Cannula for Organ Perfusion is a single-use device indicated for hypothermic flushing and replacement of residual blood in donor organs with a legally marketed organ preservation solution at the time of organ removal from the donor during the preparation of these organs for transplantation. This device is indicated for use with gravity flow; no testing has been provided for use with pump systems, such as mechanical perfusion devices.

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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K203262 -- 510(k) Summary

Date prepared: June 16, 2021

Submitter / Contact Person	H. Carl Jenkins The Wood Burditt Group 10 E. Scranton Ave, Suite 201 Lake Bluff, IL 60044 (ph) 847-234-7500 x 205 (fax) 847-578-0728 (email) hcjenkins@woodburditt.com

Applicant & 510(k) Owner	Bridge to Life Ltd. 128 Suber Rd., Suite A Columbia, SC 29210 (ph) 847-796-3070 FDA Establishment Registration Number: 3009110022 FEI Number: 3009110022 Owner/Operator Number: 10038889

Device Information

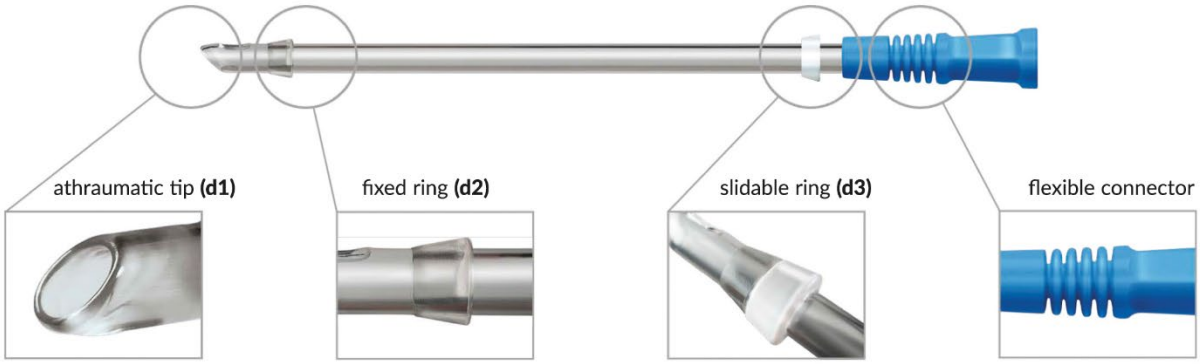
Trade Name	Cannula For Organ Perfusion
Proprietary Name	Cannula For Organ Perfusion
Common Name	Organ Perfusion Cannula
Classification Name	Isolated Kidney Perfusion and Transport System and Accessories
Classification Panel	Gastroenterology/Urology
Regulation	21 CFR 876.5880
FDA Product Code	KDN; MSB
FDA Classification	II

Reason for 510(k) Submission

The applicant device is a new device.

Device Description

The Cannula for Organ Perfusion is a device designed and intended as a component to an organ perfusion and transport system / organ preservation solution, used in an organ transplantation procedure. The device is a cannula (available in several different sizes) intended for flushing and replacement of residual blood in donor organs with organ preservation solution during the preparation processes of these organs for transplantation. The cannulas are single use, sterile, non-toxic and nonpyrogenic devices. As a component to an organ perfusion and transport system / organ preservation solution, the Cannula for Organ Perfusion is also a Class II medical device, subject to Product Code KDN and MSB, 21 CFR 876.5880: "This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set." (21 CFR 876.5880(a)).



The Cannulas come in multiple sizes, according to the French catheter scale, including 8F, 10F, 12F, 16F (adjustable to 18F with a slidable ring), 20F (adjustable to 28F with a slidable ring), 25F (adjustable to 34F with a slidable ring). In addition, there is a configuration of the cannula that is intended for "back table" procedures, which is available in a 16F size.

Cannula size	d1 mm (F)	d2 mm (F)	d3 mm (F)
8 F	2.7 (8 F)	4.7 (14 F)	—
10 F	3.3 (10 F)	5.3 (16 F)	—
12 F	4.0 (12 F)	6.3 (19 F)	—
16 F	5.3 (16 F)	7.3 (22 F)	8.7 (26 F)
20 F	6.7 (20 F)	9.3 (28 F)	10.7 (32 F)
25 F	8.3 (25 F)	11.3 (34 F)	13.3 (40 F)

The surgeon performing the organ perfusion procedure will select the appropriate cannula for the particular organ to be perfused.

Indications for Use:

Cannula for Organ Perfusion is a single-use device indicated for hypothermic flushing and replacement of residual blood in donor organs with a legally marketed organ preservation solution at the time of organ removal from the donor during the preparation of these organs for transplantation. This device is indicated for use with gravity flow; no testing has been provided for use with pump systems, such as mechanical perfusion devices.

Predicate / Reference Device Summary Table

Based on the comparison of the device features, materials, intended use and performance the Cannula for Organ Perfusion was shown to be substantially equivalent to the lawfully marketed predicate devices indicated in the table below.

Device	Applicant	510(k) #	Featured Element(s) of Substantial Equivalence
Cannula Accessory of the LifePort Kidney Perfusion Transporter	Organ Recovery Systems, Inc.	K021362	Intended Use / Indications for Use
Fresenius Multiorgan Perfusion Cannula	Fresenius	K902394	Intended Use / Indications for Use; Technology; Design

Technological Characteristics and Comparison:

The Cannula for Organ Perfusion is substantially equivalent to the cannula accessory of the LifePort Kidney Perfusion Transporter—specifically, the perfusion cannula component of the LifePort Kidney Perfusion Transporter—in terms of intended use, indications for use, FDA classification and FDA Product Code. Like the subject device, the cannula accessory of the LifePort Kidney Perfusion Transporter is used for flushing and replacement of residual blood in donor organs with organ preservation solution during the preparation processes of these organs for transplantation.

In addition, a comparison of the subject device to the Fresenius Multiorgan Perfusion Cannula demonstrates the safety and efficacy of the Cannula for Organ Perfusion in terms of substantially equivalent design, technology, use and suitability.

Feature	Subject Device	Predicate / Reference Devices
Intended Use / Indications	Cannula for Organ Perfusion is a single-use device indicated for hypothermic flushing and replacement of residual blood in donor organs with a legally marketed organ preservation solution at the time of organ removal from the donor during the preparation of these organs for transplantation. This device is indicated for use with gravity flow; no testing has been provided for use with pump systems, such as mechanical perfusion devices.	LifePort Kidney Perfusion Transporter (K021362): System component cannula for organ perfusion, intended to be used in an organ transplantation procedure. -------- Fresenius Multiorgan Perfusion Cannula (K902394): "For placement in the [organ] of a heart beating cadaver to allow in situ flushing of the cadaver organs with organ preservation solution."
Single Use / Disposable	Single Use / Disposable	Fresenius Multiorgan Perfusion Cannula (K902394): Single Use / Disposable
Device Design	The Cannula for Organ Perfusion has a tapered connector at proximal end of the cannula, and an atraumatic distal end; cone shaped.	Fresenius Multiorgan Perfusion Cannula (K902394): Perfusion cannula has a proximal end which consists of a funnel-shaped connector (i.e., a cone shape) Perfusion cannula has a distal end which consists of an atraumatic tip and cone-shaped cuff.
Sterilization	Ethylene Oxide SAL 1 x 10^{-6}	Fresenius Multiorgan Perfusion Cannula (K902394): Ethylene Oxide SAL 1 x 10^{-6}
Regulation	21 CFR 876.5880	LifePort Kidney Perfusion Transporter (K021362): 21 CFR 876.5880

FDA Product Code	KDN; MSB	LifePort Kidney Perfusion Transporter (K021362): KDN
FDA Classification	II	LifePort Kidney Perfusion Transporter (K021362): II Fresenius Multiorgan Perfusion Cannula (K902394): II

Clinical Testing:

No clinical tests were conducted in support of this 510(k) submission.

Non-Clinical Tests Performed:

Bench testing demonstrates that the Cannula for Organ Perfusion is safe, effective and meets device specifications:

- Testing related to tensile strength yielded Pass results in accordance with ISO 10555-1.
- Testing related to leakage and tightness yielded Pass results in accordance with ISO 10555-1.
- Testing related to flow rate demonstrated adequate flow of liquid in accordance with ISO 10555-1.

Sterilization & Shelf Life:

Product is sterilized using ETO, with a Sterility Assurance Level (SAL) of 10^{-6}.

The shelf life of the product has been established in accordance with real time aging testing results.

Biocompatibility:

All component materials of this medical device carry adequate quality certificates confirming their biological, physical-chemical and mechanical properties, and they are all intended for ETO sterilization.

In particular, the materials used in the manufacturing of the cannula comply with requirements of EN ISO 10993-1.

In accordance with ISO 10993-1, the Cannula for Organ Perfusion is classified as:

- surgical invasive medical device
- having external contact with the body through the circulating blood,
- remaining in contact with the body for up to 24 hours.

The following biological tests were selected for the Cannula for Organ Perfusion:

- cytotoxicity
- sensitizing effect
- intracutaneous reactivity
- systemic (acute) toxicity
- blood compatibility
- rabbit pyrogenicity

In accordance with ISO 10993-1:2009, all tests were performed using the final product after the sterilization process of the product, using a validated sterilization process.

Additionally, the manufacturer has conducted a separate biological evaluation of the subject medical device. This study included the defined requirements, product classification, description of the adopted test selection criteria, specifications and approvals of materials used to manufacture the evaluated product, a list and summary of biological tests collected or performed and analysis of the data obtained from the evaluation.

Conclusion:

The applicant device is substantially equivalent in its intended use, technology / principal of operation, materials, and performance to the predicate and reference devices identified in this 510(k) submission. There is no significant difference that raises any issues of safety or effectiveness.