January 13, 2023

Health Line International Corporation
Aaron Faulkner
Vice-President, Quality Assurance and Regulatory Affairs
260 North Ace Yeager Court, Unit D
Salt Lake City, Utah 84116

Re: K222170
Trade/Device Name: Power Acute Triple Lumen Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: December 14, 2022
Received: December 15, 2022

Dear Aaron Faulkner:

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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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)* K222170

Device Name
Power Acute Triple Lumen Hemodialysis Catheter

Indications for Use *(Describe)*
The Power Acute Triple Lumen Hemodialysis Catheter is indicated for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

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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510(k) SUMMARY
(21 CFR 807.92)

SUBMITTER	Name:	Health Line International Corporation
	Address:	260 North Ace Yeager CT, Unit D Salt Lake City, Utah 84116 USA
	FDA Registration #:	3010882065
	Contact Name:	Aaron G. Faulkner Vice-President, Quality Assurance and Regulatory Affairs
	Telephone:	801-773-7798 Ext. 109
	Fax:	855-228-1336
	Email:	agfaulkner@hlic.net
	Date Prepared:	July 19, 2022
SUBJECT DEVICE	Name:	***Power Acute Triple Lumen Hemodialysis Catheter***
	Regulation Name:	Blood access device and accessories
	Classification Name:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
	Classification Panel:	Gastroenterology/Urology
	Regulatory Class:	Class II
	Product Code:	NIE
	Regulation Number:	21 CFR 876.5540
PREDICATE DEVICE	Name:	***Mahurkar™ Triple Lumen Dialysis Catheter (K102605) by Covidien, LLC***
	Regulation Name:	Blood access device and accessories
	Classification Name:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
	Classification Panel:	Gastroenterology/Urology
	Regulatory Class:	Class II
	Product Code:	NIE
	Regulation Number:	21 CFR 876.5540
	Recall Event ID:	82802
REFERENCE DEVICE A	Name:	***Power-Trialysis™ Slim-Cath™ Short-Term Dialysis Catheter (K141531) by C.R. Bard, Inc.***
	Regulation Name:	Blood access device and accessories
	Classification Name:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
	Classification Panel:	Gastroenterology/Urology
	Regulatory Class:	Class II
	Product Code:	NIE
	Regulation Number:	21 CFR 876.5540

	Recall Event ID:	No recall has been issued to K141531
REFERENCE DEVICE B	Name:	***Acute Dual Lumen Hemodialysis Catheter (K200426) by Health Line International Corporation***
	Regulation Name:	Blood access device and accessories
	Classification Name:	Catheter, Hemodialysis, Non-Implanted
	Classification Panel:	Gastroenterology/Urology
	Regulatory Class:	Class II
	Product Code:	MPB
	Regulation Number:	21 CFR 876.5540
	Recall Event ID:	No recall has been issued to K200426

DEVICE DESCRIPTION

The *Power Acute Triple Lumen Hemodialysis Catheter* is manufactured from a thermally reactive polyurethane material known for its rigidity at room temperature and softness at body temperature. This reactivity allows bedside insertion, while minimizing the risk of vein perforation and providing an overall improvement of patient comfort after insertion. The catheter cannula is radiopaque and incrementally marked to indicate the effective insertion length of the device in centimeters (cm). This cannula is extruded with three independent, non-communicating inner lumens. The lumens are made accessible within the cannula via luer-fitted silicone extension legs on the proximal end of the device, alongside a rigid polyurethane hub marked with the catheter's size in French (Fr) and effective insertion length that is fitted with a freely rotating suture wing. The clear outer extension legs are fitted with red and blue occlusion clamps, which are marked on either face with the lumen's priming volume in milliliters (mL), and respectively identify arterial and venous lumens. The medial, colored, extension leg is fitted with a purple occlusion clamp that is similarly marked with priming volume on its dorsal face, and marked with the maximum flow rate (in cubic centimeters [cc]) and injection pressure (in pounds per square inch [psi]) recommended for power-injected fluids on its ventral face. The distal end of the device is thermally bonded to a flexible, symmetrically tapered tip, which allows for direct outflow, and is skived on the radial and ulnar sides of the cannula.

The size configuration for the *Power Acute Triple Lumen Hemodialysis Catheter* is shown in the following table.

SUBJECT DEVICE CONFIGURATION					
SIZE (Fr)	**LENGTH (cm)**				
12	12	15	20	24	30

INTENDED USE

The *Power Acute Triple Lumen Hemodialysis Catheter* is intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring, and pressure injection of contrast media. The

maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

INDICATIONS FOR USE

The *Power Acute Triple Lumen Hemodialysis Catheter* is indicated for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring, and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

TECHNOLOGICAL CHARACTERISTICS

Subject Device: *Power Acute Triple Lumen Hemodialysis Catheter*
Predicate Device: *Mahurkar™ Triple Lumen Dialysis Catheter (K102605)*

ATTRIBUTES	SUBJECT DEVICE	PREDICATE DEVICE
Intended use	The *Power Acute Triple Lumen Hemodialysis Catheter* is intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring, and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.	The *Mahurkar™ Triple Lumen Dialysis Catheter* is intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.
Intended duration	Short term (< 30 days)	Short term (< 30 days)
Intended treatment	Acute condition	Acute condition
Prescription device	Yes	Yes
Insertion sites	Internal jugular Subclavian Femoral	Internal jugular Subclavian Femoral
Insertion technique	Seldinger (Over the guidewire)	Seldinger (Over the guidewire)
Intended population	Adults	Adults
Catheter size	12 Fr	12 Fr
Catheter OD	4.20 mm	4.15 mm
Catheter lengths available (cm)	12, 15, 20, 24, 30	13, 16, 20, 24
Catheter length for comparison	24 cm	24 cm

Catheter shaft effective length	24 cm	24 cm
Insertion markings	Every centimeter	None
Catheter shaft material	Polyurethane	Polyurethane
Catheter/Extension configuration	Straight Extensions Curved Extensions	Straight Extensions Curved Extensions
Catheter cuffed	No	No
Tip design	Symmetrical soft tapered tip	Symmetrical soft tapered tip
Tip placement	The distal tip should be located just before the junction of the superior vena cava and the right atrium	The distal tip should be located just before the junction of the superior vena cava and the right atrium
Number of lumens	3	3
Lumen identification	Color coded clamps: Red (Arterial) Blue (Venous) Purple (Medial)	Color coded luer connectors: Red (Arterial) Blue (Venous) Clear (Medial)
Extension legs (Venous, Arterial)	Silicone	Silicone
Extension leg (Medial)	Polyurethane	Polyurethane
Cross-section geometry	Modified Double “D” with Center Lumen	Modified Double “D” with Off-Center Lumen
Sterilization method	Ethylene Oxide	Ethylene Oxide
Method of use	Single use	Single use
Shelf life	3 years	5 years
Primary packaging	Tyvek Tray	Tyvek Tray
Catheter side openings	4 holes	2 holes 1 slot
Luer Connectors	ISO 594-1 Compatible	ISO 594-1 Compatible
Non-Pyrogenic	Yes	Yes
Made with latex rubber	No	No
Made with DEHP	No	No
Power Injection (PI)	Yes	Yes
Max PI infusion rate	5 mL/sec	5 mL/sec
Max PI pressure	300 psi	300 psi

	The subject device has similar technological characteristics as compared to the predicate device. Differences, if any, are not critical to the intended use of the subject device (see Section 12.7, Substantial Equivalence Discussion) and do not raise new questions regarding safety and effectiveness.
SAFETY AND PERFORMANCE TESTING	The *Power Acute Triple Lumen Hemodialysis Catheter* followed verification and validation activities in accordance with Design Controls as per 21 CFR Section 820.30. Bench testing was conducted in accordance with FDA-recognized consensus standards to evaluate the performance of the subject device on: - Air Leakage - Liquid Leakage - Tensile Strength - Catheter Flow Rate - Priming Volume - Kinking - Repeated Clamping - Conical Luer Lock Fittings - Surface Appearance - Chemical Tolerance - Power Injection Performance - Static Burst Pressure - Recirculation Rate - Central Venous Pressure Monitoring - Pressure vs Flow Rate Functional testing was conducted in accordance with ISO 11135 and ISO 11607-1 to evaluate sterilization and shelf life of the subject device. Biocompatibility testing and assessment was conducted in accordance with ISO 10993-1 to evaluate the subject device on: - Cytotoxicity - Sensitization - Irritation or Intracutaneous Reactivity - Acute Systemic Toxicity - Material Mediated Pyrogen - Bacterial Endotoxin Testing - Subacute Toxicity - Subchronic Toxicity - Genotoxicity - Intramuscular Implantation - Hemocompatibility, Hemolysis Direct Contact - Hemocompatibility, Hemolysis Indirect Contact

	- Hemocompatibility, Thrombogenicity In Vitro Blood Loop Assay - Hemocompatibility, Complement Activation - Hemocompatibility, Mechanically Induced Hemolysis - Chronic Toxicity - Carcinogenicity Results of the functional, performance and biocompatibility testing support the determination of substantial equivalence.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	In accordance with FDA 21 CFR Section 807.92, and based on the indications for use, technological characteristics, and safety and performance testing, the subject *Power Acute Triple Lumen Hemodialysis Catheter* met the minimum requirements that are considered adequate for its intended use and is *substantially equivalent* in design, materials, sterilization, principles of operation, and indications for use to the currently marketed predicate device.