December 24, 2020

Health Line International Corporation
Aaron Faulkner
Director of Engineering
5675 West 300 South
Salt Lake City, UT 84104

Re: K200426
Trade/Device Name: Acute Dual Lumen Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: November 23, 2020
Received: November 25, 2020

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize), you must submit a new 510(k) before including these components in your kit. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200426

Device Name

Acute Dual Lumen Hemodialysis Catheter

Indications for Use *(Describe)*

The Acute Dual Lumen Hemodialysis Catheter is indicated for short-term central venous access for hemodialysis, apheresis, and infusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
(21 CFR 807.92)

SUBMITTER	Name:	Health Line International Corporation
	Address:	5675 West 300 South Salt Lake City, Utah 84104
	FDA Registration #:	3010882065
	Contact Name:	Aaron G. Faulkner Director of Engineering
	Telephone:	801-773-7798 Ext. 109
	Fax:	855-228-1336
	Email:	agfaulkner@hlic.net
	Date Prepared:	February 19, 2020
SUBJECT DEVICE	Name:	***Acute Dual Lumen Hemodialysis Catheter***
	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
PREDICATE DEVICE	Name:	***Mahurkar™ Elite Acute Dual Lumen Catheter (K120674) by Covidien LLC***
	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 k120674
REFERENCE DEVICE	Name:	***Niagara™ Slim-Cath® Short-Term Dialysis Catheter (k010778) by C.R. Bard, INC***
	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 k010778
DEVICE DESCRIPTION	The *Acute Dual Lumen Hemodialysis Catheter* is manufactured from thermal reactive polyurethane material known for its rigidity at room	

temperature which allows bedside insertion, and softness at body temperature minimizing the risk of vein perforation and improving patient comfort after insertion. The catheter shaft is made of radiopaque polyurethane with two independent, non-communicating inner lumens, where the distal end of the catheter, with arranged outflow eyelets, extends to a symmetrical tip configuration. The proximal end of the catheter shaft joins to a polyurethane hub assembly having each inner lumen connected to individual extension tubes. The extension tubes are made of silicone material and are identified by color coded occlusion clamps. The red clamp identifies the lumen which provides "arterial" outflow from the patient, the blue clamp identifies the lumen which provides "venous" inflow return when used for hemodialysis, apheresis and infusion. Lumen priming volume is printed on each ID tag clamp insert, and catheter size and length are printed in the hub. Centimeter markings are placed along the length of the indwelling portion of the catheter body to facilitate proper positioning.

The size configuration for the *Acute Dual 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 *Acute Dual Lumen Hemodialysis Catheter* is intended to be used for short-term central venous access for hemodialysis, apheresis, and infusion.

INDICATIONS FOR USE

The *Acute Dual Lumen Hemodialysis Catheter* is indicated for short-term central venous access for hemodialysis, apheresis, and infusion.

TECHNOLOGICAL CHARACTERISTICS

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, Substantial Equivalence Discussion) and do not raise new questions regarding safety and effectiveness.

Subject Device: *Acute Dual Lumen Hemodialysis Catheter*
Predicate Device: *Mahurkar™ Elite Acute Dual Lumen Catheter (K120674)*

	ATTRIBUTES	SUBJECT DEVICE	PREDICATE DEVICE
TECHNOLOGICAL CHARACTERISTICS	Intended use	The *Acute Dual Lumen Hemodialysis Catheter* is intended to be used for short-term central venous access for hemodialysis, apheresis, and infusion.	The *Mahurkar™ Elite Acute Dual Lumen Catheter* is intended to be used for short-term central venous access for hemodialysis, apheresis, and infusion.
	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	4.10 mm
	Catheter lengths available (cm)	12, 15, 20, 24, 30	13, 16, 20, 24, 30
	Catheter length for comparison	20 cm, 24cm	20 cm, 24cm
	Catheter shaft effective length	20 cm, 24cm	20 cm, 24cm
	Insertion markings	Every centimeter	Every centimeter
	Catheter shaft material	Polyurethane	Polyurethane
	Catheter/Extension configuration	Straight extensions Curved extensions Pre-Curved catheter	Straight extensions Curved extensions Pre-Curved catheter
	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	2	2
	Lumen identification	Color coded clamps:	Color coded Luer connectors:

	Red (Arterial) Blue (Venous)	Red (Arterial) Blue (Venous)
Extension legs (Venous, Arterial)	Silicone	Silicone
Cross-section geometry	Modified Double "D"	Double "D"
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	3 holes (1 venous and 2 arterials)	2 Slots (1 venous and 1 arterial)
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 Injectable	No	No

SAFETY AND PERFORMANCE TESTING

The *Acute Dual 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 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
- Recirculation Rate
- 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, Thrombogenecity 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 *Acute Dual 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.