DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 1, 2016

L&Z US, Inc.
Ms. Jenella Coutts
Director of Regulatory Affairs
6 Horizon Road, #2301
Fort Lee, New Jersey 07024

Re: K153469
Trade/Device Name: CATHTONG™ I PICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 29, 2016
Received: August 3. 2016

Dear Ms. Coutts:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153469

Device Name
CATHTONG™ I PICC Catheter

Indications for Use *(Describe)*
The CATHTONG™ I PICC Catheter is intended for short or long-term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, power injection of contrast media, the administration of fluids, medications and nutrients, and allows for central venous pressure monitoring. The maximum recommended infusion rate is 1mL/sec for 3F and 3.5mL/sec for 4F single-lumen catheters. The maximum pressure of power injection with the CATHTONG™ I PICC Catheter may not exceed 325 psi. The CATHTONG™ I PICC Catheter is indicated for adult patients.

Catheter Size Maximum Flow Rate Injection Limit Setting
3 Fr Single Lumen 1 ml/sec 325 psi
4 Fr Single Lumen 3.5 ml/sec 325 psi

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

Submitter Information: L&Z US, Inc.

6 Horizon Road, #2301
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Contact Person: Jenella Coutts

Director of Regulatory Affairs

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Fax Number: **(**718) 228-2441

Date of Submission: August 31, 2016

Trade Name: CATHTONG™ I PICC Catheter

Common Name: Peripherally Inserted Central Catheter (PICC)

Regulation Number: 21 CFR 880.5970

Regulation Name: Percutaneous, implanted, long-term intravascular catheter

Regulatory Class: II

Product Code: LJS

Classification Panel: General Hospital

Primary Predicate: **NMI PICC IV**
Common Name: Peripherally Inserted Central Catheter (PICC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Classification Panel: General Hospital
510(K) #: K140266
Manufacturer: Navilyst Medical, Inc.

Device Description:

CATHTONG™ I PICC Catheters are radiopaque polyurethane-based peripherally inserted central venous catheters for short or long-term use. The CATHTONG™ I PICC

Catheters are 55 cm in length with markings in 5 cm increments and available in 3 Fr and 4 Fr single lumen. The catheter is packaged as a kit with accessories necessary for implantation of a PICC catheter using a Seldinger or modified Seldinger technique.

Intended Use/Indications for Use:

The CATHTONG™ I PICC Catheter is intended for short or long-term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, power injection of contrast media, the administration of fluids, medications and nutrients, and allows for central venous pressure monitoring. The maximum recommended infusion rate is 1mL/sec for 3F and 3.5mL/sec for 4F single-lumen catheters. The maximum pressure of power injection with the CATHTONG™ I PICC Catheter may not exceed 325 psi. The CATHTONG™ I PICC Catheter is indicated for adult patients.

Catheter Size	Maximum Flow Rate	Injection Limit Setting
3 Fr Single Lumen	1 mL/sec	325 psi
4 Fr Single Lumen	3.5 mL/sec	325 psi

Table E-1 Device comparisons table

Characteristics	**Subject Device:** **CATHTONG™ I PICC Catheter**	**Primary Predicate :** **NMI PICC IV** **K140266** **SE 03.05.2014**

Indications for Use Statement	The CATHTONG™ I PICC Catheter is intended for short or long-term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, power injection of contrast media, the administration of fluids, medications and nutrients, and allows for central venous pressure monitoring. The maximum recommended infusion rate is 1mL/sec for 3F and 3.5mL/sec for 4F single-lumen catheters. The maximum pressure of power injection with the CATHTONG™ I PICC Catheter may not exceed 325 psi. The CATHTONG™ I PICC Catheter is indicated for adult patients. Catheter Size: 3 Fr Single Lumen Maximum Flow Rate 1 mL/sec, Injection Limit Setting 325 psi. Catheter Size 4 Fr Single Lumen, Maximum Flow Rate 3.5 mL/sec, Injection Limit Setting 325 psi.	The NMI PICC IV is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media. The maximum recommended flow rate is 1mL/sec for 3F and 3.5mL/sec for 4F. The maximum pressure of injection with the NMI IV PICC catheter may not exceed 325 psi.
Dwell Time	Short or long-term (Less than or greater than 30 days)	Short or long-term (Less than or greater than 30 days)
Regulation	21CFR880.5970 Percutaneous, implanted, long-term intravascular catheter	Same
Product Code	LJS	LJS
Target Population	Adults	Adults
Catheter Materials	Radiopaque polyurethane (Carbothane)	Radiopaque polyurethane
Length	55 cm (3F), 55cm (4F)	55 cm (3F), 55cm(4F)
# Lumens and catheter size	One (3F, 4F)	One (3F, 4F, 5F), Two (5F, 6F), Three (6F)
Markings	Every 5 cm	Every 5 cm
Catheter Design	Standard tapered catheter	Reverse tapered catheter
Contrast Injectables	Yes	Yes

Supplied Sterile (Sterilization Method)	Provided sterile using EO sterilization Method	Provided sterile using EO sterilization Method
Labeling Shelf-Life	16 Months	6 Months
Accessories in Package	Guidewire Straight Tip, Guidewire, Multi Compartment Tray, Micro Access with Dilator, Introducer Needle, Needle Receptacle, Safety Scalpel, Syringe, Scissors, Instructions For Use, SorbaView® Ultimate Dressing, Universal Tape Strip, Wingguard® Xtra, Tape Measure, Fenestrated Drape	"Available kitted with a range of procedural accessories for user convenience"
Maximum recommended infusion rating for power injection	3F SL: 1mL/sec 4F SL: 3.5mL/sec	3F SL: 1mL/sec 4F SL: 3.5mL/sec
Injection Pressure Limit Setting	325 psi	325 psi
Available performance data to support SE determination	Yes	Yes
Special labeling performance claim	None	"Demonstrate resistance to blood components (platelet and thrombus) accumulation"

Similarity to the Predicate

The proposed device, CATHTONG™ I PICC Catheter, has the same intended use, intended function, catheter length, maximum recommended infusion rating, pressure limit for power injection of contrast media and are also made of the same materials as the primary predicate device, NMI PICC IV. They both are intended for short or long-term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, power injection of contrast media, and allow for central venous pressure monitoring in adult patients. There are no changes in the fundamental clinical indications for both PICC catheters. There are no

additional contra-indications or warnings. Both devices are sterilized by ethylene oxide with acceptable low EO residues.

Difference to the Predicate

The only differences between the proposed device and the predicate are the number of the lumen, the catheter size, the taper design, the accessories in the kit package, and special functional performance claim. The proposed device has only one single lumen configuration with 3F and 4F sizes, while the predicate device has single, double and triple lumen configurations with 3F, 4F, 5F and 6F sizes. The proposed device and the predicate do differ in that the predicate has a reverse tapered catheter design while the proposed device is the standard tapered design. However, upon testing both proposed and the predicate devices maintained identical maximum flow rates, therefore this different design feature does not dispute equivalence. In terms of kit package content, the proposed PICC device contains Guidewire Straight Tip, Guidewire, Multi Compartment Tray, Micro Access with Dilator, Introducer Needle, Needle Receptacle, Safety Scalpel, Syringe, Scissors, Instructions For Use, SorbaView® Ultimate Dressing, Universal Tape Strip, Wingguard® Xtra, Tape Measure, Fenestrated Drape in its kit package, while the predicate contains "a range of procedural accessories for user convenience". In addition, the predicate device makes "resistance to blood components (platelet and thrombus) accumulation" labeling claim, while the proposed device does not make any functional performance claim.

Non-clinical Testing:

- Flexural fatigue and flexibility
- Peak tensile force
- Liquid leakage under pressure
- Air leakage

- Flow rate
- Power injection - Burst pressure
- Power injection - Flow rate
- Catheter collapse
- Radiopacity
- Gauging
- Irritation/Intracutaneous Reactivity
- Cytotoxicity Test (MEM Elution)
- Partial Thromboplastin Time (PTT)
- Material Mediated Pyrogen Test
- Kligman Maximization Test
- Intramuscular Implantation Test 13 Week Implantation
- 28-Day Systemic Toxicity in Rats via Intramuscular Implantation
- Systemic Injection Test
- Liquid Leakage
- Separation Force
- Unscrewing Torque
- Ease of Assembly
- Resistance to Overriding
- Stress Cracking
- Salmonella Typhirmurium and Escherichia Coli Reverse Mutation Assay
- C3A and SCB-9 Complement Activation Test (Direct Contact)
- Rabbit Blood Hemolysis Test
- Thrombogenicity Study in Swine
- Mouse Lymphoma Mutagenesis Assay with Confirmation
- Rodent Blood Micronucleus Assay
- LAL Testing for Pyrogenicity

Standards:

ISO 10551 -1:2013 *Sterile, single-use intravascular catheters Part 1: General Requirements*
ISO 10551 -3: 2013 *Sterile, single-use intravascular catheters Part 3: Central venous catheters*
ISO 594-1: 1986 *Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment Part 1: General Requirements.*
ISO 594-2: 1998 *Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment Part 2: Lock Fittings*
FDA's *"Guidance on Premarket Notification [510(k)] Submissions for Short-term and Long-term Intravascular Catheters, dated March 16, 1995.*
ISO 10993-3, 2014 *Biological Evaluation of Medical Devices- Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity*
ISO/TR 10993-33, 2015 *Biological Evaluation of Medical Devices- Part 33: Guidance on Tests to Evaluate Genotoxicity – Supplement to ISO 10993-3*
ISO 10993-4, 2006 *Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, as amended 2006*
ISO 10993-5:2009 *Biological Evaluation of Medical Devices Part 5; Tests for In Vitro Cytotoxicity*
ISO 10993-6, 2007 *Biological Evaluation of Medical Devices Part 6: Tests for Local Effects after Implantation*
ISO 10993-10:2010 *Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization*
ISO 10993-11:2006 *Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity*
ISO 11135-1:2007 *Sterilization of health care products – Ethylene oxide Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices*

Substantial Equivalence Rationale:

Intended Use

The intended use of the proposed device, CATHTONG™ I PICC Catheter, is identical to the primary predicate, NMI PICC IV (K140266). There are no changes in the fundamental clinical indications. There are no additional contraindications or warnings.

Design and Technological Characteristics

The CATHTONG™ I PICC Catheter has the same catheter material (polyurethane), dimensions, configuration, and device properties as the predicate. The only minor design difference is the standard tapered catheter design for the proposed device versus reverse tapered catheter design for the predicate. However, this does not impact the effectiveness or safety of the proposed device as upon testing both devices safely maintained identical maximum flow rates.

Non-clinical Test Results

The non-clinical test results in this submission demonstrate that CATHTONG™ I PICC Catheter meets the expected performance requirements for a PICC device, and is therefore substantially equivalent to the predicate relative to safety and mechanical properties as a PICC.

Conclusion

Based upon the indications for use, technological characteristics, and non-clinical testing the CATHTONG™ I PICC Catheter has demonstrated to be Substantially Equivalent to the predicate device, NMI PICC IV (K140266).