August 3, 2017

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

Re: K172039
   Trade/Device Name: CATHTONG™ II PICC Catheter
   Regulation Number: 21 CFR 880.5970
   Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
   Regulatory Class: Class II
   Product Code: LJS
   Dated: June 27, 2017
   Received: July 5, 2017

Dear Jenella 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,

James P. Bertram -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known)
K172039

Device Name
CATHTONG™ II PICC Catheter

indications for Use (Describe)
The CATHTONG™ II 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 3.0 mL/sec for 3F and 5.0 mL/sec for 4F single lumen catheters. The maximum pressure of power injection with the CATHTONG™ II PICC Catheter may not exceed 325 psi. The CATHTONG™ II PICC Catheter is indicated for adult patients.

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Maximum Flow Rate</th>
<th>Injection Limit Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>3F Single Lumen</td>
<td>3.0 mL/sec</td>
<td>325 psi</td>
</tr>
<tr>
<td>4F Single Lumen</td>
<td>5.0 mL/sec</td>
<td>325 psi</td>
</tr>
</tbody>
</table>

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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