December 1, 2022

SILQ Technologies, Corp.
% Aaron Rogers
Director of Regulatory and Quality
Pathway LLC
8779 Cottonwood Ave, Suite 105
Santee, California 92071

Re: K222118
Trade/Device Name: 2-Way 100% Silicone Cleartract Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: October 25, 2022
Received: October 25, 2022

Dear Aaron Rogers:

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,

Jessica K. Nguyen -S

Jessica Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K222118

Device Name
2-Way 100% Silicone Cleartract Catheter

Indications for Use *(Describe)*
The 2-Way 100% Silicone ClearTract Catheter is intended for drainage of the urinary tract. Catheterization is generally accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic placement or other placement of the catheter, such as nephrostomy tract. Intended population is adults and pediatrics.

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

DATE PREPARED December 1, 2022

1. SUBMITTER INFORMATION

APPLICANT

SILQ Technologies, Corporation
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OFFICIAL CORRESPONDENT

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2. SUBJECT DEVICE INFORMATION

DEVICE TRADE NAME 2-Way 100% Silicone ClearTract Catheter

COMMON NAME Foley Catheter

CLASSIFICATION NUMBER 21 CFR §876.5130

CLASSIFICATION NAME Urological Catheter and Accessories

PRODUCT CODE EZL

PRODUCT CODE NAME Catheter, Retention Type, Balloon

REGULATORY CLASS II

3. PREDICATE DEVICE INFORMATION

PREDICATE DEVICE IDENTIFICATION 2-Way 100% Silicone ClearTract Catheter (K221625)

REFERENCE DEVICE IDENTIFICATION PSM 3-Way Silicone Foley Catheter (K181616)

4. DESCRIPTION OF SUBJECT DEVICE

The 2-Way 100% Silicone ClearTract Catheter is a standard single-use 2-way Foley catheter that is constructed of medical grade silicone with a surface modification. It incorporates two (2) lumens, one for inflation/deflation of the balloon and the other for drainage of the urinary tract. The drainage inlet is located distal to the catheter's balloon. The connection to the urinary bag is a standard non-interconnectable connector.

The objective of this 510(k) was only to update the indications for use (IFU) statement to include bladder urine drainage by either suprapubic or nephrostomy in addition through the urethra. No changes were made to the device design, manufacture or any of its physical attributes when compared to the predicate device.

5. INDICATIONS FOR USE

The 2-Way 100% Silicone ClearTract Catheter is intended for drainage of the urinary tract. Catheterization is generally accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic placement or other placement of the catheter, such as nephrostomy tract. Intended population is adults and pediatrics.

6. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Comparison Item	**Subject Device: 2-Way 100% Silicone ClearTract Catheter**	**Predicate Device: 2-Way 100% Silicone ClearTract Catheter**	**Reference Device: PSM 3-Way Silicone Foley Catheter**
510(k) Number	K222118	K221625	K181616
Indications for Use	The 2-Way 100% Silicone ClearTract Catheter is intended for drainage of the urinary tract. Catheterization is generally accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic placement or other placement of the catheter, such as nephrostomy tract. Intended population is adults and pediatrics.	The 2-Way 100% Silicone ClearTract Catheter is intended for drainage of the urinary tract. Catheterization is accomplished by inserting the catheter through the urethra and into the bladder. Intended population is adults and pediatrics.	Urological catheter intended for drainage/irrigation of the urinary tract. Catheterization is accomplished through the urinary tract, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.
Design Features			
Type	Same as Predicate	2-Way Foley Catheter with inflation and drainage lumens	3-Way Foley Catheter with inflation, drainage and irrigation lumens
Size/Balloon	Same as Predicate	14Fr/10cc 16Fr/5cc 18Fr/10cc	14Fr/10cc – 30cc 16Fr/10cc-30cc 18Fr/10cc-30cc
Materials of Construction	Same as Predicate	Silicone, Medical Grade	Silicone, Medical Grade

Comparison Item	Subject Device: 2-Way 100% Silicone ClearTract Catheter	Predicate Device: 2-Way 100% Silicone ClearTract Catheter	Reference Device: PSM 3-Way Silicone Foley Catheter
Zwitterionic Polymer Surface Modification	Same as Predicate	Yes	No
Performance Standard	Same as Predicate	ASTM F623	ASTM F623
Indwelling Time	Same as Predicate	Up to 30 days	Up to 30 days
Single Use?	Same as Predicate	Yes	Yes
Prescription Use?	Same as Predicate	Yes	Yes
Sterile?	Same as Predicate	Yes	Yes
Sterilization Method	Same as Predicate	Ethylene Oxide Gas	Ethylene Oxide Gas

7. SUMMARY OF NON-CLINICAL TESTING

The following testing was performed to support the additional indications for use.

- Biocompatibility Genotoxicity Study per 10993-3:2014, Biological Evaluation of Medical Devices, Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- Bacterial Endotoxins Test (BET) / Limulus amebocyte lysate (LAL) test per USP <85>.

8. CONCLUSIONS

All changes were made in compliance with 21 CFR 820.30 for design controls. Based on a risk assessment, the proposed additions to the indications for use do not change or add new risks to the ClearTract catheter All testing was successfully completed and provided objective evidence to demonstrate the ClearTract catheter is substantially equivalent to the predicate device.