



January 23, 2024

Silq Technologies Corporation
% Aaron Rogers
Director of Regulatory and Quality
Pathway, LLC.
8779 Cottonwood Avenue, Suite 105
Santee, CA 92071

Re: K233013
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: December 18, 2023
Received: December 19, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 K. 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

Indications for Use

510(k) Number (if known)

K233013

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 accomplished by inserting the catheter through the urethra and into the bladder, but also suprapubic placement or by nephrostomy. 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(K) SUMMARY**1. SUBMITTER INFORMATION**

Applicant	SILQ Technologies, Corporation 323 Sunny Isles Blvd., 7th Floor Sunny Isles Beach, FL 33160
Official Correspondent	Aaron Rogers Pathway, LLC. 8779 Cottonwood Ave., Suite 105 Santee, CA 92071 619-415-0103 x704 arogers@pathwaynpi.com
Date Prepared	January 16, 2024

2. DEVICE NAME

Trade Name of the Device	2-Way 100% Silicone Cleartract Catheter
Common Name:	Foley Catheter
Classification Name:	Urological Catheter and Accessories
Classification Regulation:	21 CFR 876.5130
Device Class:	II
Product Code:	EZL
Panel:	Gastroenterology/Urology

**3. PREDICATE AND REFERENCE
DEVICE IDENTIFICATION**

Predicate: 2-Way 100% Silicone Cleartract Catheter ([K222118](#))
Reference: Silicone Foley Catheter for single use ([K172807](#))

4. DEVICE DESCRIPTION:

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 between the catheter and the urinary bag is accomplished by using a standard non- interconnectable connector. Catheterization is accomplished by inserting the catheter through the urethra. Drainage can also be accomplished by suprapubic placement or nephrostomy tract placement of the catheter.

Catheter sizes 14Fr., 16Fr., and 18Fr. were cleared under the predicate, K222118. Subject catheter of size 24 Fr. is new and being requested for clearance as part of this submission.

5. INDICATIONS FOR USE:

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, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Comparison Element	Subject Device: 2-Way 100% Silicone ClearTract Catheter	Predicate Device: 2-Way 100% Silicone ClearTract Catheter	Reference Device: Silicone Foley Catheter for single use
510(k) Number	K233013	K222118	K172807
Indications for Use	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, but also suprapubic placement or by nephrostomy. 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, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.	Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwelling time is no more than 30 days. Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwelling time is no more than 30 days.
Device Type	2-Way Foley Catheter with inflation and drainage lumens	2-Way Foley Catheter with inflation and drainage lumens	2-Way with inflation and drainage lumens 3-Way with inflation, drainage and irrigation lumens
Size	24Fr	14Fr, 16Fr, 18Fr	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr
Balloon Volume	30ml	5ml, 10ml	3ml, 5ml, 10ml, 15ml, 30ml
Length	405 mm	405 mm	400 mm
Materials of Construction	Silicone, Medical Grade	Silicone, Medical Grade	Silicone, Medical Grade
Polymer Surface Modification	Yes	Yes	No
Indwelling Time	Up to 30 days	Up to 30 days	Up to 30 days
Single Use?	Yes	Yes	Yes
Prescription Use?	Yes	Yes	Yes
Sterile?	Yes	Yes	Yes

As evidenced by the above table, both the subject and the predicate devices have same intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. SUMMARY OF NONCLINICAL TESTING:

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process* and FDA Guidance “*Use of International Standard ISO 10993-1*” (2016).
- The EO sterilization process was validated in accordance with ANSI/AAMI/ISO 11135:2014.
- The following bench performance testing were conducted per ASTM F623-19 and the FDA guidance document, ‘*Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway*’-
 - Flow Rate through Drainage Lumen
 - Balloon Integrity (Resistance to Rupture)
 - Inflated Balloon Response to Traction
 - Balloon Volume Maintenance
 - Balloon Size and Shaft Size
 - Deflation Reliability (Failure to Deflate)

All pre-determined acceptance criteria were met.

8. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.
