July 1, 2022

Silq Technologies Corporation
Sigi Caron, MBA, RAC
Vice President of Regulatory Affairs
323 Sunny Isles Blvd.
Sunny Isles Beach, FL 33160

Re: K221625
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: June 3, 2022
Received: June 6, 2022

Dear Sigi Caron:

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,

For,
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

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)*

K221625

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. 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.

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1. SPECIAL 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

DATE PREPARED	June 16, 2022
APPLICANT	Silq Technologies Corporation 323 Sunny Isles Blvd, 7th Floor Sunny Isles, FL 33160
OFFICIAL CORRESPONDENT	Sigi Caron, MBA, RAC Biologics and Medical Device Consulting Group (BioMDg) 377 Second Tee Dr, #5868 Incline Village, NV 89451 *phone:* (831) 346-6970 *e-mail:* sigi@bioMDg.com
TRADE NAME	2-Way 100% Silicone ClearTract Catheter
COMMON NAME	Foley Catheter
DEVICE CLASSIFICATION	Name: Urological Catheter and Accessories Regulation No: 21 CFR §876.5130 Product Code: EZL – Catheter, Retention Type, Balloon Class: II
PREDICATE DEVICE	HDX 100% Silicone 2-Way Foley Catheter (K192034)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The 2-Way 100% Silicone ClearTract Catheter (previously known as the HDX 100% Silicone 2-Way Foley 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.

INDICATIONS FOR USE:

The indications for use remain the same. 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.

PREDICATE DEVICE

The renamed 2-Way 100% Silicone ClearTract Catheter has not been modified in any way. It is exactly the same as the HDX 100% Silicone 2-Way Catheter cleared under 510(k)

premarket notification K192034.

SUMMARY OF MODIFICATIONS

This special 510(k) premarket notification only proposes an update to the product labeling. The following information has been added to the Instructions For Use:

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."*

Performance Characteristics - *"The surface of the ClearTract Catheter has a surface modification that reduces surface friction."*

No physical changes or modifications are proposed to the cleared device.

PERFORMANCE STANDARDS:

No performance standards have been established by the Agency to date that apply to this device.

SUMMARY OF NONCLINICAL TESTING:

The following bench testing was performed to support the additional information added to the product labeling:

- Friction testing based on ASTM D1894-14 which demonstrates a significant reduction in the coefficient of friction between the untreated and treated silicone surface.

SUBSTANTIAL EQUIVALENCE – COMPARISON TO PREDICATE DEVICE

The 2-Way 100% Silicone ClearTract Catheter has not been modified in any way. It is exactly the same as the HDX 100% Silicone 2-Way Catheter cleared under 510(k) premarket notification K192034. Following is the SE Table.

Element	Subject Device: 2-Way 100% Silicone ClearTract Catheter	Predicate Device: HDX 100% Silicone 2-Way Foley Catheter	Comparison
510(k) Number	K221625	K192034	----
Indications for use	… 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.	… 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.	Same
Design Features			
Type	2-Way Foley Catheter with inflation and drainage lumens	2-Way Foley Catheter with inflation and drainage lumens	Same
Size/Balloon	14Fr/10cc 16Fr/5cc 18Fr/10cc	14Fr/10cc 16Fr/5cc 18Fr/10cc	Same
Material of Construction	Silicone, Medical Grade	Silicone, Medical Grade	Same
Zwitterionic Polymer Surface Modification	Yes	Yes	Same
Performance Standard	ASTM F623	ASTM F623	Same
Single Use?	Yes	Yes	Same
Prescription Use?	Yes	Yes	Same
Sterile?	Yes	Yes	Same
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas	Same

CONCLUSION:

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