FDA 510(k) Premarket Notification

K222118 2-Way 100% Silicone Cleartract Catheter

CLEARED

Dec 1, 2022
136 days to decision

K222118 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222118/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 18, 2022
Decision date	Dec 1, 2022
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Silq Technologies, Corp.**
Location	Sunny Isles Beach, FL, US
Contact	D. Verne Sharma
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Pathway, LLC**
Contact	Aaron Rogers

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov