FDA 510(k) Premarket Notification

K182635 Signal Catheter

CLEARED

Jan 10, 2019
108 days to decision

K182635 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k182635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 24, 2018
Decision date	Jan 10, 2019
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Safe Medical Design**
Location	San Francisco, CA, US
Contact	Raymond "Buzz" Bonneau
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Allison Komiyama

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