FDA 510(k) Premarket Notification

K181750 SITZMARKS

CLEARED

Nov 15, 2018
136 days to decision

K181750 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 2, 2018
Decision date	Nov 15, 2018
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Konsyl Pharmaceuticals**
Location	Easton, MD, US
Contact	Frank Gunsallus III
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Prism Medical Device Consulting**
Contact	Stuart Portnoy

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