

K181750 SITZMARKSNov 15, 2018
136 days to decisionK181750 · 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](https://accessdata.fda.gov)

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