

K183072 EndoFLIP SystemFeb 15, 2019
102 days to decisionK183072 · Product code: **FFX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Nov 5, 2018
Decision date	Feb 15, 2019
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Crospon, Ltd.
Location	Bonita Springs, FL, US
Contact	John O'apos;Dea
510(k) history	12 submissions · 12 cleared · 2009-2019

REGULATORY CONSULTANT

Consulting firm	Medtronic
Contact	Avishag Metzger

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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