FDA 510(k) Premarket Notification

K183072 EndoFLIP System

CLEARED

Feb 15, 2019
102 days to decision

K183072 · 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'Dea
510(k) history	12 submissions · 12 cleared · 2009-2019

REGULATORY CONSULTANT

Consulting firm	**Medtronic**
Contact	Avishag Metzer

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