FDA 510(k) Premarket Notification

K182022 ApexMV

CLEARED

Mar 15, 2019
231 days to decision

K182022 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k182022/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jul 27, 2018
Decision date	Mar 15, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Incontrol Medical, LLC**
Location	Brookfield, WI, US
Contact	Corey Olson
510(k) history	7 submissions · 6 cleared · 2012-2019