

K182022 ApexMVMar 15, 2019
231 days to decisionK182022 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182022/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026