

K234061 StarFormerJul 1, 2024
192 days to decisionK234061 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k234061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Dec 22, 2023
Decision date	Jul 1, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fotona D.O.O.
Location	Ljubljana, SI
Contact	Tina Bartolic
510(k) history	16 submissions · 16 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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