FDA 510(k) Premarket Notification

K234061 StarFormer

CLEARED

Jul 1, 2024
192 days to decision

K234061 · Product code: **KPI** · Gastroenterology & Urology
Source: 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