FDA 510(k) Premarket Notification

K241899 Pelvic Floor Stimulator (Intrelief PFE)

CLEARED

Nov 27, 2024
152 days to decision

K241899 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241899/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jun 28, 2024
Decision date	Nov 27, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Easymed Instruments Co., Ltd.**
Location	Daliang, Shunde, Foshan, Guang Dong, CN
Contact	Tingjie Wu
510(k) history	3 submissions · 3 cleared · 2014-2024