FDA 510(k) Premarket Notification

K191312 Perfect PFE

CLEARED

Nov 1, 2019
170 days to decision

K191312 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k191312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	May 15, 2019
Decision date	Nov 1, 2019
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tenscare, Ltd.**
Location	Timperley, Cheshire, GB
Contact	Andrew Brown
510(k) history	13 submissions · 13 cleared · 2001-2024