FDA 510(k) Premarket Notification

K213133 Keffort (MC-100, MC-100A)

CLEARED

Apr 13, 2022
198 days to decision

K213133 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213133/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 27, 2021
Decision date	Apr 13, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Oriental Inspiration Limited**
Location	Hong Kong, CN
Contact	Francis Ko
510(k) history	5 submissions · 5 cleared · 2017-2024