FDA 510(k) Premarket Notification

K230767 Pelvic Floor Muscle Stimulator

CLEARED

Sep 21, 2023
185 days to decision

K230767 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230767/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Mar 20, 2023
Decision date	Sep 21, 2023
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nanjing Vishee Medical Technology Co., Ltd.**
Location	Nanjing, CN
Contact	Qiu Kai
510(k) history	2 submissions · 2 cleared · 2023-2023