FDA 510(k) Premarket Notification

CLEARED

K252552 Pelvic Floor Rehabilitation Therapy Device (PD2301/PD2302/PD2303)

May 6, 2026
266 days to decision

K252552 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Aug 13, 2025
Decision date	May 6, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Changkun Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Qingpeng Wang
510(k) history	6 submissions · 6 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Mgmt Consulting Co., Ltd.**
Contact	Reanny Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov