FDA 510(k) Premarket Notification

CLEARED

K252831 Pelvic Floor Treatment Device (DLR-8920, DLR-8921, DLR-8922, DLR-8923, DLR-8924, DLR-8925, DLR-8926, DLR-8927)

Apr 28, 2026
235 days to decision

K252831 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252831/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 5, 2025
Decision date	Apr 28, 2026
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Dolanvy (Suzhou) Medical Technology Co., Ltd.**
Location	Suzhou, CN
Contact	Ji Lei
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Shanghai SUNGO Management Consulting Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov