FDA 510(k) Premarket Notification

CLEARED

K252334 PELVIPOWER Pelvic Functional Magnetic Stimulation (PELVIPOWER PelvicFMS) (033-0-1100-02)

Apr 17, 2026
263 days to decision

K252334 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jul 28, 2025
Decision date	Apr 17, 2026
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pontemedag**
Location	Arbon, CH
Contact	Remo Schneider
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Adrienne Lenz

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