

K252601 Pelvic Muscle Trainer (PC22A)May 14, 2026
269 days to decisionK252601 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Aug 18, 2025
Decision date	May 14, 2026
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pelvic Muscle Trainer (PC22A-L); Pelvic Muscle Trainer (PC22E); Pelvic Muscle Trainer (PC22E-L)

APPLICANT

Company	Hunan Accurate Bio-Medical Technology Co., Ltd.
Location	Changsha, Hunan, CN
Contact	Li Zhang
510(k) history	6 submissions · 6 cleared · 2014-2026

REGULATORY CONSULTANT

Consulting firm	Chonconn Consulting Co., Ltd.
Contact	Jie Yang

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

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