

K252748 Pelvic Floor Exerciser (PF01)Apr 27, 2026
241 days to decisionK252748 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Aug 29, 2025
Decision date	Apr 27, 2026
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Accurate Bio-Medical Technology Co., Ltd.
Location	Changsha, Hunan, CN
Contact	Li Zhang
510(k) history	5 submissions · 5 cleared · 2014-2026

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