

K200409 Pelvital SystemJul 10, 2020
142 days to decisionK200409 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k200409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Feb 19, 2020
Decision date	Jul 10, 2020
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pelvital USA, Inc.
Location	Minneapolis, MN, US
Contact	Dale Wahlstrom
510(k) history	5 submissions · 5 cleared · 2020-2024

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