

**K212655 Flyte**Sep 21, 2021  
29 days to decisionK212655 · Product code: **HIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212655/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Perineometer (HIR)
Date received	Aug 23, 2021
Decision date	Sep 21, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Winegar Consulting, Inc.</b>
Contact	Mike Winegar

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026