

**K233362 Flyte Mechanotherapy System (aka Flyte System)
(MTI-1.0)**Dec 29, 2023
88 days to decisionK233362 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Perineometer (HIR)
Date received	Oct 2, 2023
Decision date	Dec 29, 2023
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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