FDA 510(k) Premarket Notification

K240805 Flyte Mechanotherapy System, MTI-1.5 (MTI-1.5)

CLEARED

Aug 1, 2024
129 days to decision

K240805 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Mar 25, 2024
Decision date	Aug 1, 2024
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Ming Cheng Chew

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