FDA 510(k) Premarket Notification

K212655 Flyte

CLEARED

Sep 21, 2021
29 days to decision

K212655 · Product code: **HIR** · Gastroenterology & Urology
Source: 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	**Pelvital USA, Inc.**
Location	Minneapolis, MN, US
Contact	Dale Wahlstrom
510(k) history	5 submissions · 5 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**Winegar Consulting, Inc.**
Contact	Mike Winegar

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