FDA 510(k) Premarket Notification

K210764 Flyte

CLEARED

Apr 13, 2021
29 days to decision

K210764 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Perineometer (HIR)
Date received	Mar 15, 2021
Decision date	Apr 13, 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

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Device record: https://www.510kdatabase.net/k210764/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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