

K252005 Livi DeviceMar 20, 2026
266 days to decisionK252005 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jun 27, 2025
Decision date	Mar 20, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Liviwell, Inc.
Location	Mountain Lakes, NJ, US
Contact	Michael Ingber
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory and Technical Associates
Contact	Chris Staab

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252005/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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