

K242105 SABA TamponsApr 1, 2025
257 days to decisionK242105 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k242105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 18, 2024
Decision date	Apr 1, 2025
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Essity Higiene Y Salud Mexico. S.A. DE C.V.
Location	Cuidad De Mexico, MX
Contact	Sean Anderson
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	NJK & Associates, Inc.
Contact	Natalie Kennel

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

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