

K252613 Unscented menstrual three-piece applicator tamponSep 19, 2025
31 days to decisionK252613 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 19, 2025
Decision date	Sep 19, 2025
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unibeauty (Hubei) Technology Co., Ltd.
Location	Xiantao, CN
Contact	Guofeng Ou
510(k) history	4 submissions · 4 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Jiushun Enterprise Management Technology Service
Contact	Doris Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026