

K241064 Unscented TamponJan 10, 2025
267 days to decisionK241064 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Apr 18, 2024
Decision date	Jan 10, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Intco Hygiene Products Co., Ltd.
Location	Zibo, CN
Contact	Max Li
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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