

K212277 Tempo TamponApr 21, 2022
275 days to decisionK212277 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k212277/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 20, 2021
Decision date	Apr 21, 2022
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dong-A Pharmaceutical Co., Ltd.
Location	Seoul, KR
Contact	Hyunjeong Jang
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Provision Consulting Group, Inc.
Contact	Joyce Kwon

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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