

K212272 Tempo Natural TamponSep 17, 2021
59 days to decisionK212272 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212272/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 20, 2021
Decision date	Sep 17, 2021
Days to decision	59 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212272/> 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 26, 2026