

K182817 CottonDay TamponJul 22, 2019
292 days to decisionK182817 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k182817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Oct 3, 2018
Decision date	Jul 22, 2019
Days to decision	292 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taebong Co., Ltd.
Location	Gwangju Gwangyeoksi, KR
Contact	Ha Neul Jeong
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Provision Consulting Group, Inc.
Contact	Joyce Kwun

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/k182817/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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