

K230419 Sequel Tampon with Plastic ApplicatorAug 3, 2023
168 days to decisionK230419 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k230419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Feb 16, 2023
Decision date	Aug 3, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tampro, Inc.
Location	San Francisco, CA, US
Contact	Greta Meyer
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory and Technical Associates
Contact	Chris Staab

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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