

K211519 Every Cycle Reusable Tampon ApplicatorAug 13, 2021
88 days to decisionK211519 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	May 17, 2021
Decision date	Aug 13, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cycle, LLC
Location	Santa Monica, CA, US
Contact	Jessica Samson
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	NJK & Associates, Inc.
Contact	Gabriela McCoolle

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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