

**K212304 Callaly Tampliner (super plus absorbency)**Aug 19, 2021  
27 days to decisionK212304 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 23, 2021
Decision date	Aug 19, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Calla Lily Personal Care, Ltd.</b>
Location	London, GB
Contact	Shaun Knights
510(k) history	3 submissions · 3 cleared · 2020-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>2Harris Consulting, Ltd.</b>
Contact	Kathleen Harris

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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