

K211469 Callaly TamplinerJun 10, 2021
30 days to decisionK211469 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211469/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	May 11, 2021
Decision date	Jun 10, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	2Harris Consulting, Ltd.
Contact	Kathleen Harris

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/k211469/> 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