

K191666 Unscented W long plastic and cardboard applicator tamponsDec 20, 2019
182 days to decisionK191666 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jun 21, 2019
Decision date	Dec 20, 2019
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ontex Bvba
Location	Old Lyme, CT, US
Contact	Henri Lesage
510(k) history	6 submissions · 6 cleared · 2012-2019

REGULATORY CONSULTANT

Consulting firm	Emergo Europe Consulting
Contact	Rachel Paul

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191666/> 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 June 28, 2026