

K122603 ONTEX AND OTHER PROPRIETARY NAMESDec 19, 2012
114 days to decisionK122603 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k122603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 27, 2012
Decision date	Dec 19, 2012
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122603/> 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