

**K132595 ONTEX ROLL WADDING PLASTIC APPLICATOR
COMPACT SIZE UNSCENTED TAMPONS**Apr 23, 2014
247 days to decisionK132595 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 19, 2013
Decision date	Apr 23, 2014
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132595/> 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