

K142786 Ontex Unscented Tampons with Colored Plastic Applicators

Jun 23, 2015
270 days to decisionK142786 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k142786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Sep 26, 2014
Decision date	Jun 23, 2015
Days to decision	270 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142786/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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