

K162746 Ontex and other proprietary namesMar 3, 2017
154 days to decisionK162746 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k162746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Sep 30, 2016
Decision date	Mar 3, 2017
Days to decision	154 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

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