

**K132208 ONTEX AND OTHERS PROPRIETARY NAMES**Apr 10, 2014  
268 days to decisionK132208 · Product code: **HIL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132208/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Tampon, Menstrual, Scented, Scented-deodorized (HIL) |
| Date received         | Jul 16, 2013   |
| Decision date         | Apr 10, 2014   |
| Days to decision      | 268 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132208/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026