

**K172504 Tosama Biobased Applicator Tube Menstrual Tampon**Feb 9, 2018  
175 days to decisionK172504 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k172504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 18, 2017
Decision date	Feb 9, 2018
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tosama, D.O.O.</b>
Location	Vir, Domzale, SI
Contact	Marjetka Kralj Kuncic
510(k) history	5 submissions · 5 cleared · 2012-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172504/> 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 May 27, 2026