

**K232060 TOSAMA Reusable Applicator**Apr 12, 2024  
276 days to decisionK232060 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 11, 2023
Decision date	Apr 12, 2024
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tosama, D.O.O.</b>
Location	Vir, Domzale, SI
Contact	Janez Obreza
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/k232060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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