

**K222046 Unscented Menstrual Tampon**Sep 30, 2022  
81 days to decisionK222046 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 11, 2022
Decision date	Sep 30, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Borage Medical Technology Co., Ltd.</b>
Location	Suzhou, CN
Contact	Zhou Nana
510(k) history	2 submissions · 2 cleared · 2022-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Grace Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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