

**K182142 FEMME Applicator Tampon**Aug 28, 2019  
386 days to decisionK182142 · Product code: **HEB** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k182142/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 7, 2018
Decision date	Aug 28, 2019
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Yoai Technology Co., Ltd.</b>
Location	Nanjing, CN
Contact	Huan Wang
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Field Fu

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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