

**K212479 Cohitech Reusable Tampon Applicator**Oct 8, 2021  
60 days to decisionK212479 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Aug 9, 2021
Decision date	Oct 8, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cotton High Tech S.L.</b>
Location	Barcelona, ES
Contact	Anna Garcia
510(k) history	7 submissions · 7 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212479/> 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 26, 2026