

**K200672 Durex Penck Standard, Durex Penck XL**Nov 6, 2020  
238 days to decisionK200672 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200672/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 13, 2020
Decision date	Nov 6, 2020
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rb Health (Us), LLC</b>
Location	Parsippany, NJ, US
Contact	Kyle Prince
510(k) history	14 submissions · 14 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200672/> 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 25, 2026