

**K222611 Male Latex Condoms**Nov 28, 2022  
90 days to decisionK222611 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Aug 30, 2022
Decision date	Nov 28, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Colour-Way New Material Co., Ltd.</b>
Location	Suzhou, CN
Contact	Yongping Xu
510(k) history	3 submissions · 3 cleared · 2022-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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