

**K182438 Synthetic Polyisoprene Lubricated Male Condom - 5 senses**Dec 6, 2018  
90 days to decisionK182438 · Product code: **MOL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k182438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom, Synthetic (MOL)
Date received	Sep 7, 2018
Decision date	Dec 6, 2018
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>Sxwell USA, LLC</b>
Location	Iselin, NJ, US
Contact	Robert Mahler
510(k) history	2 submissions · 2 cleared · 2017-2018

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182438/> 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 June 28, 2026