

**K132107 MALE LATEX CONDOM**Mar 7, 2014  
242 days to decisionK132107 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132107/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jul 8, 2013
Decision date	Mar 7, 2014
Days to decision	242 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nulatex Sdn. Bhd.</b>
Location	Kluang, Johor, MY
Contact	AI SIANG TEO
510(k) history	3 submissions · 3 cleared · 2007-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132107/> 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 7, 2026