

**K010919 MALE NATURAL RUBBER LATEX CONDOM**Jun 15, 2001  
80 days to decisionK010919 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k010919/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Mar 27, 2001
Decision date	Jun 15, 2001
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Innolates Sdn. Bhd</b>
Location	Shah Alam, Selangor Darul Ehsan, MY
Contact	CHANG AH-KAU
510(k) history	9 submissions · 9 cleared · 2000-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010919/> 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 29, 2026