

**K012664 ULTRA THICK MALE LATEX CONDOM WITH SILICONE LUBRICANT**Nov 9, 2001  
88 days to decisionK012664 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k012664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Aug 13, 2001
Decision date	Nov 9, 2001
Days to decision	88 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/k012664/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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