

K010178 SPERMICIDAL LUBRICATED MALE LATEX CONDOMApr 27, 2001
98 days to decisionK010178 · Product code: **LTZ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k010178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom With Nonoxynol-9 (LTZ)
Date received	Jan 19, 2001
Decision date	Apr 27, 2001
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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