

**K012964 56MM CONDOM,MALE NATURAL RUBBER LATEX
CONDOM**Nov 9, 2001
66 days to decisionK012964 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k012964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Sep 4, 2001
Decision date	Nov 9, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012964/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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