

**K002393 NON-SPERMICIDAL LUBRICATED MALE LATEX
CONDOM**Dec 19, 2000
134 days to decisionK002393 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k002393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 7, 2000
Decision date	Dec 19, 2000
Days to decision	134 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/k002393/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026