

**K972836 ROYALE BRAND LATEX CONDOMS-SPERMICIDAL  
LUBRICANT - COLORED OR ASSORTED COLORS**Oct 22, 1997  
83 days to decisionK972836 · Product code: **LTZ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k972836/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom With Nonoxynol-9 (LTZ)
Date received	Jul 31, 1997
Decision date	Oct 22, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>G. Premjee (Usa), Inc.</b>
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	2 submissions · 2 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972836/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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