

**K971132 ROYALE BRAND LATEX CONDOMS
(SILICONE)-COLORED/ASSORTED COLORS**Sep 3, 1997
160 days to decisionK971132 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k971132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 27, 1997
Decision date	Sep 3, 1997
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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