

**K983320 ROYALE BRAND LATEX CONDOMS SILICONE
LUBRICANT COLORED-OR ASSORTED COLORS**Dec 11, 1998
81 days to decisionK983320 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k983320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Sep 21, 1998
Decision date	Dec 11, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Suretex Prophylactics (India) , Ltd.
Location	Bangalore, Karnataka, IN
Contact	V.V. RAMANA RAO
510(k) history	3 submissions · 3 cleared · 1998-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983320/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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