

K981621 ROYALE OF LATEX CONDOMS - SPERMICIDAL LUBRICANT - COLORED OR ASSORTED COLORSJun 19, 1998
44 days to decisionK981621 · Product code: **LTZ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k981621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom With Nonoxynol-9 (LTZ)
Date received	May 6, 1998
Decision date	Jun 19, 1998
Days to decision	44 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

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