

**K010371 LIFESTYLES, CONTEMPO OR PRIVATE LABEL, MALE
LATEX CONDOM WITH GLYCERINE LUBRICANT**Apr 27, 2001
79 days to decisionK010371 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k010371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Feb 7, 2001
Decision date	Apr 27, 2001
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Suretex, Ltd.
Location	Avondale, AZ, US
Contact	LON D MCILVAIN
510(k) history	5 submissions · 5 cleared · 1991-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010371/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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