

K992081 VARIOUS ANSELL TRADENAMES OR PRIVATE LABELAug 19, 1999
59 days to decisionK992081 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k992081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jun 21, 1999
Decision date	Aug 19, 1999
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992081/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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