

**K970633 TUSTEX FLAVORED CONDOMS**Mar 21, 1997  
29 days to decisionK970633 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k970633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 20, 1997
Decision date	Mar 21, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Line One Laboratories</b>
Location	Los Angeles, CA, US
Contact	ROBERT GRUBER
510(k) history	5 submissions · 5 cleared · 1997-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970633/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026