

**K922889 CONDOOM SHELF LIFE -- MODIFICATIONS**Sep 1, 1993  
467 days to decisionK922889 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k922889/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	May 22, 1992
Decision date	Sep 1, 1993
Days to decision	467 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Safetex Corp.</b>
Location	Colonial Heights, VA, US
Contact	DAVIS
510(k) history	7 submissions · 7 cleared · 1990-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922889/> 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 30, 2026