

**K970767 CONDOM (RUBBER), LUBRICATED, EXTRA STRENGTH**Jun 2, 1997  
91 days to decisionK970767 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k970767/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 3, 1997
Decision date	Jun 2, 1997
Days to decision	91 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Custom Services Intl., Inc.</b>
Location	Las Vegas, NV, US
Contact	LILLIE C THOMAS
510(k) history	9 submissions · 9 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970767/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 29, 2026