

**K972428 EXTRAWEAR, GENTLEMEN'S CHOICE**Aug 25, 1997  
59 days to decisionK972428 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k972428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jun 27, 1997
Decision date	Aug 25, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**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/k972428/> 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