

**K980319 DUREX ULTRA COMFORT**May 20, 1998  
113 days to decisionK980319 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k980319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jan 27, 1998
Decision date	May 20, 1998
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>London Intl., LLC</b>
Location	Dothan, AL, US
Contact	NEIL ANDERSON, RAC
510(k) history	6 submissions · 6 cleared · 1998-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980319/> 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