

**K864400 EXTRA STRONG CONDOM**Feb 2, 1987  
88 days to decisionK864400 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k864400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Nov 6, 1986
Decision date	Feb 2, 1987
Days to decision	88 days
Third-party review	No

**APPLICANT**

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Company	<b>Ansell, Inc.</b>
Location	Dothan, AL, US
Contact	BRADLEY PUGH
510(k) history	30 submissions · 30 cleared · 1980-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864400/>, 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