

**K884401 SKIN LESS SKIN CONDOM W/SPERMICIDAL LUBRICANT**Jan 12, 1989  
85 days to decisionK884401 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k884401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Oct 19, 1988
Decision date	Jan 12, 1989
Days to decision	85 days
Third-party review	No

**APPLICANT**

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Company	<b>Okamoto USA, Inc.</b>
Location	Stratford, CT, US
Contact	JEFFREY N GIBBS
510(k) history	14 submissions · 14 cleared · 1987-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884401/>; 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 May 27, 2026