

**K911431 TACTYLON(TM) CONDOM**Dec 27, 1994  
1365 days to decisionK911431 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k911431/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Apr 2, 1991
Decision date	Dec 27, 1994
Days to decision	1365 days
Third-party review	No

**APPLICANT**

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Company	<b>Tactyl Technologies, Inc.</b>
Location	Vista, CA, US
Contact	BUDDENHAGEN
510(k) history	7 submissions · 7 cleared · 1990-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911431/>, 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