

**K895894 PROFIL CONDOM (RUBBER LATEX)**Dec 14, 1989  
70 days to decisionK895894 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k895894/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Oct 5, 1989
Decision date	Dec 14, 1989
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Rfsu</b>
Location	Stockholm, SE
Contact	NILS DIDING
510(k) history	5 submissions · 5 cleared · 1989-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895894/>; 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 30, 2026