

**K971979 PLAYTEX TAMPONS #14897/PLAYTEX GENTLE  
GLIDE,SILK GLIDE, SLIMFITS,SOFT COMFORT AND  
PORTABLES TAMPONS**Sep 26, 1997  
120 days to decisionK971979 · Product code: **HIB** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k971979/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	May 29, 1997
Decision date	Sep 26, 1997
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Playtex Products, Inc.</b>
Location	Paramus, NJ, US
Contact	MARK E ROSENGARTEN
510(k) history	17 submissions · 17 cleared · 1995-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971979/>; 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 26, 2026