

**K980478 PLAYTEX TAMPONS #03498**Apr 3, 1998  
56 days to decisionK980478 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k980478/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Feb 6, 1998
Decision date	Apr 3, 1998
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Playtex, Inc.</b>
Location	Mchenry, IL, US
Contact	MARK ROSENGARTEN
510(k) history	20 submissions · 18 cleared · 1981-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980478/> 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 14, 2026