

**K013289 BIOTEQUE VAGINAL PESSARIES**Dec 27, 2001  
86 days to decisionK013289 · Product code: **HHW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k013289/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Oct 2, 2001
Decision date	Dec 27, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bioteque America, Inc.</b>
Location	Levittown, PA, US
Contact	DENIS DORSEY
510(k) history	10 submissions · 10 cleared · 1992-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013289/> 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