

**K862478 HAYES VAGINAL SHIELD**Nov 24, 1986  
147 days to decisionK862478 · Product code: **HDF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k862478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Metal (HDF)
Date received	Jun 30, 1986
Decision date	Nov 24, 1986
Days to decision	147 days
Third-party review	No

**APPLICANT**

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Company	<b>Franklin Medical USA, Inc.</b>
Location	Atlanta, GA, US
Contact	HAYES, M.D.
510(k) history	4 submissions · 3 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862478/>; 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