

**K093218 FEMEYE TWO**May 18, 2010  
217 days to decisionK093218 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k093218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 13, 2009
Decision date	May 18, 2010
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fem Suite, LLC</b>
Location	Port Townsend, WA, US
Contact	PAVAN SETHI
510(k) history	2 submissions · 2 cleared · 2007-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093218/> 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 21, 2026