

**K945131 IMAGYN INTRAUTERINE INSEMINATION DEVICE**May 15, 1995  
208 days to decisionK945131 · Product code: **HDR** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k945131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Cervical (HDR)
Date received	Oct 19, 1994
Decision date	May 15, 1995
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imagyn Medical, Inc.</b>
Location	San Clemente, CA, US
Contact	DEBRA A RINDERER
510(k) history	19 submissions · 19 cleared · 1991-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945131/> 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