

**K965055 IMAGYN MICROLAP AND MICRO LAP-GOLD  
LAPAROSCOPES**

Mar 6, 1997  
78 days to decision

K965055 · Product code: **HET** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k965055/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Dec 18, 1996
Decision date	Mar 6, 1997
Days to decision	78 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/k965055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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