

K943810 IMAGYN MICROLAP INTRODUCERJan 26, 1995
174 days to decisionK943810 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k943810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Aug 5, 1994
Decision date	Jan 26, 1995
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imagyn Medical, Inc.
Location	San Clemente, CA, US
Contact	ROBERT J CHIN
510(k) history	19 submissions · 19 cleared · 1991-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943810/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026