

K971255 IMAGYN EXPANDABLE LAPAROSCOPIC INTRODUCERApr 21, 1997
17 days to decisionK971255 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k971255/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, Gynecologic (and Accessories) (HET) |
| Date received | Apr 4, 1997 |
| Decision date | Apr 21, 1997 |
| Days to decision | 17 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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