

**K972426 MICROSPAN GOLD HYSTEROSCOPE AND
MICROSPAN HYSTEROSCOPE SHEATH**Sep 23, 1997
88 days to decisionK972426 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k972426/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received | Jun 27, 1997 |
| Decision date | Sep 23, 1997 |
| Days to decision | 88 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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