

K122973 AL-106, AL-106SA AND AL-106B MEDGYN DIGITAL VIDEO COLPOSCOPEJun 12, 2013
259 days to decisionK122973 · Product code: **HEX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k122973/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colposcope (and Colpomicroscope) (HEX) |
| Date received | Sep 26, 2012 |
| Decision date | Jun 12, 2013 |
| Days to decision | 259 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medgyn Products, Inc. |
| Location | Downers Grove, IL, US |
| Contact | STEPHANIE BLAIR |
| 510(k) history | 5 submissions · 5 cleared · 1988-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122973/> 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 3, 2026