

K011512 MMODIFICATION TO LAMINARIAJul 9, 2001
54 days to decisionK011512 · Product code: **HDY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k011512/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dilator, Cervical, Hygroscopic-laminaria (HDY) |
| Date received | May 16, 2001 |
| Decision date | Jul 9, 2001 |
| Days to decision | 54 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | A & A Medical, Inc. |
| Location | Branford, CT, US |
| Contact | JIHAD (JAY) MANSOUR |
| 510(k) history | 23 submissions · 23 cleared · 1988-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011512/> 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