

K052420 G-SPEC ARTICULATED WEIGHTED VAGINAL SPECULUMApr 6, 2006
216 days to decisionK052420 · Product code: **HIB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k052420/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Speculum, Vaginal, Nonmetal (HIB) |
| Date received | Sep 2, 2005 |
| Decision date | Apr 6, 2006 |
| Days to decision | 216 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Gynova, LLC |
| Location | Manchester, CT, US |
| Contact | DON GUINAN |
| 510(k) history | 1 submissions · 1 cleared · 2006-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052420/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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