

K061339 HIERSPEC SPECULUMSep 19, 2006
127 days to decisionK061339 · Product code: **HIB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k061339/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Speculum, Vaginal, Nonmetal (HIB) |
| Date received | May 15, 2006 |
| Decision date | Sep 19, 2006 |
| Days to decision | 127 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medical Products Div. |
| Location | Indianapolis, IN, US |
| Contact | THOMAS W COPELAND |
| 510(k) history | 1 submissions · 1 cleared · 2006-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061339/> 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