

K033728 TRANSVAGINAL ENDOSCOPY SETFeb 27, 2004
91 days to decisionK033728 · Product code: **HEW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k033728/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culdoscope (and Accessories) (HEW) |
| Date received | Nov 28, 2003 |
| Decision date | Feb 27, 2004 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | KARL STORZ Endoscopy-America, Inc. |
| Location | Mchenry, IL, US |
| Contact | YVONNE FERNANDEZ |
| 510(k) history | 361 submissions · 361 cleared · 1980-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033728/> 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 May 14, 2026