

K191294 Transvaginal Access PlatformSep 6, 2019
115 days to decisionK191294 · Product code: **HEW** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191294/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culdoscope (and Accessories) (HEW) |
| Date received | May 14, 2019 |
| Decision date | Sep 6, 2019 |
| Days to decision | 115 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Applied Medical Resources Corp. |
| Location | Rancho Santa, CA, US |
| Contact | Corinne Yestrepky |
| 510(k) history | 45 submissions · 45 cleared · 2001-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191294/> 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