

K083690 FEMVUE(TM) CATHETER SYSTEMJun 23, 2009
193 days to decisionK083690 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k083690/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cannula, Manipulator/injector, Uterine (LKF) |
| Date received | Dec 12, 2008 |
| Decision date | Jun 23, 2009 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Femasys, Inc. |
| Location | Suwanee, GA, US |
| Contact | MARC FINCH |
| 510(k) history | 9 submissions · 9 cleared · 2009-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083690/> 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 25, 2026