FDA 510(k) Premarket Notification

# K242002 FemVue MINI Saline-Air Device

**CLEARED**

Nov 22, 2024
136 days to decision

K242002 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k242002/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cannula, Manipulator/injector, Uterine (LKF) |
| Date received | Jul 9, 2024 |
| Decision date | Nov 22, 2024 |
| Days to decision | 136 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k242002/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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