

K221965 FemDx FalloViewMar 17, 2023
255 days to decisionK221965 · Product code: **MKO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221965/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Falloscope (MKO) |
| Date received | Jul 5, 2022 |
| Decision date | Mar 17, 2023 |
| Days to decision | 255 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Femdx Medsystems, Inc. |
| Location | Santa Clara, CA, US |
| Contact | PeiJie Cao |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Regulatory Consulting Services, LLC |
| Contact | Sevrina Ciucci |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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