

K964441 FEMRX FOCUSED MONOPOLAR (FAP) OPERASTAR SYSTEM [OUTPATIENT ENDOSCOPIC RESECTION AND ABLATION (OPERA)] [SPECIALIZED TISSUMar 28, 1997
142 days to decisionK964441 · Product code: **KNF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k964441/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF) |
| Date received | Nov 6, 1996 |
| Decision date | Mar 28, 1997 |
| Days to decision | 142 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Gynecare Innovation Center |
| Location | Sunnyvale, CA, US |
| Contact | MICHAEL A DANIEL |
| 510(k) history | 8 submissions · 8 cleared · 1996-1998 |

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