

K971305 FEMRX FOCUSED MONOPOLAR (FMP) OPERA STAR SYSTEMAug 11, 1997
125 days to decisionK971305 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k971305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 8, 1997
Decision date	Aug 11, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynecare Innovation Center
Location	Sunnyvale, CA, US
Contact	GEORGE M SAVAGE
510(k) history	8 submissions · 8 cleared · 1996-1998

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