

K954648 FEMRX OPERASTAR SYSTEMMar 14, 1996
156 days to decisionK954648 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k954648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 10, 1995
Decision date	Mar 14, 1996
Days to decision	156 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954648/> 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 June 29, 2026