

K964892 FEMRX TURP SR SYSTEM (TS27XX-YY/TS24XX-YY)Feb 4, 1997
60 days to decisionK964892 · Product code: **FJL** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resectoscope (FJL)
Date received	Dec 6, 1996
Decision date	Feb 4, 1997
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynecare Innovation Center
Location	Sunnyvale, CA, US
Contact	JOHN N ZORICH
510(k) history	8 submissions · 8 cleared · 1996-1998

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