

K953201 IMAGYN UROSCOPEAug 2, 1995
27 days to decisionK953201 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k953201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jul 6, 1995
Decision date	Aug 2, 1995
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imagyn Medical, Inc.
Location	San Clemente, CA, US
Contact	DEBRA A RINDERER
510(k) history	19 submissions · 19 cleared · 1991-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953201/> 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