

**K991929 INTRASTENT**Aug 4, 1999  
57 days to decisionK991929 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k991929/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 8, 1999
Decision date	Aug 4, 1999
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intratherapeutics, Inc.</b>
Location	Saint Paul, MN, US
Contact	CATHY YOHNK
510(k) history	15 submissions · 7 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991929/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026