

K990592 INTRASTENT IISep 1, 1999
189 days to decisionK990592 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990592/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 24, 1999
Decision date	Sep 1, 1999
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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