

K992816 MODIFICATION TO INTRASTENTOct 15, 1999
56 days to decisionK992816 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k992816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 20, 1999
Decision date	Oct 15, 1999
Days to decision	56 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992816/> 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 30, 2026