FDA 510(k) Premarket Notification

K993904 INTRASTENT DOUBLESTRUT LD

CLEARED

Feb 1, 2000
76 days to decision

K993904 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993904/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 17, 1999
Decision date	Feb 1, 2000
Days to decision	76 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.net
Device record: https://www.510kdatabase.net/k993904/ 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