

**K003997 INTRASTENT DOUBLESTRUT PARAMOUNT XS
BILIARY ENDOPROSTHESIS**Jan 24, 2001
29 days to decisionK003997 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k003997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 26, 2000
Decision date	Jan 24, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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