

**K012347 PROTEGE SELF-EXPANDING NITINOL STENT WITH
STARPORT DELIVERY TECHNOLOGY**Aug 23, 2001
30 days to decisionK012347 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k012347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 24, 2001
Decision date	Aug 23, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sulzer Intratherapeutics, Inc.
Location	Saint Paul, MN, US
Contact	MARCIA R ELLIS
510(k) history	8 submissions · 2 cleared · 2001-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012347/> 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