FDA 510(k) Premarket Notification

K012347 PROTEGE SELF-EXPANDING NITINOL STENT WITH STARPORT DELIVERY TECHNOLOGY

CLEARED

Aug 23, 2001
30 days to decision

K012347 · 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