FDA 510(k) Premarket Notification

K011806 PROTEGE SELF-EXPANDING NITINOL STENT WITH STARPORT DELIVERY TECHNOLOGY

CLEARED

Sep 7, 2001
88 days to decision

K011806 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k011806/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 11, 2001
Decision date	Sep 7, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sulzer Intratherapeutics, Inc.**
Location	Saint Paul, MN, US
Contact	MARIA E BRITTLE
510(k) history	8 submissions · 2 cleared · 2001-2002