

**K012822 MODIFICIATION TO: BILIARY WALLSTENT
ENDOPROSTHEIS WITH MONORAIL DELIVERY SYSTEM,
MODEL 71-XXX**Oct 24, 2001
62 days to decisionK012822 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k012822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 23, 2001
Decision date	Oct 24, 2001
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Scimed, Inc.
Location	Plymouth, MN, US
Contact	TODD KORNMANN
510(k) history	35 submissions · 26 cleared · 1994-2004

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