

K012216 NIROYAL BILIARY PREMOUNTED STENT SYSTEMAug 17, 2001
32 days to decisionK012216 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k012216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 16, 2001
Decision date	Aug 17, 2001
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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