FDA 510(k) Premarket Notification

K024048 MODIFICATION TO BOSTON SCIENTIFIC EXPRESS BILIARY LD PREMOUNTED STENT SYSTEM

CLEARED

Jan 6, 2003
28 days to decision

K024048 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k024048/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 9, 2002
Decision date	Jan 6, 2003
Days to decision	28 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k024048/ 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 28, 2026