

**K982005 WALLSTENT TRANSHEPATIC BILIARY
ENDOPROSTHESIS**Sep 2, 1998
86 days to decisionK982005 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k982005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 8, 1998
Decision date	Sep 2, 1998
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982005/> 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