

K862059 SHEATH, ENDOSCOPENov 4, 1986
158 days to decisionK862059 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k862059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 30, 1986
Decision date	Nov 4, 1986
Days to decision	158 days
Third-party review	No

APPLICANT

Company	Endovations
Location	Camp Hill, PA, US
Contact	KAREN S BUTT
510(k) history	37 submissions · 36 cleared · 1986-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862059/>; 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 July 1, 2026