

K033537 SELFX XPERT BILIARY STENT, MODELS EX8L2005, EX8L3005, EX8L4005, EX8L2006, EX8L3006, EX8L4006, EX8S2005, AND EX8S3005Dec 10, 2003
30 days to decisionK033537 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k033537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 10, 2003
Decision date	Dec 10, 2003
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JOANNA KUSKOWSKI
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...