

K053404 LIFESTENT FLEXSTART BILIARY STENT SYSTEMDec 21, 2005
14 days to decisionK053404 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k053404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 7, 2005
Decision date	Dec 21, 2005
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	KEVIN DRISKO
Website	https://www.edwards.com
510(k) history	135 submissions · 129 cleared · 1979-2026

Edwards Lifesciences, LLC is a global structural heart innovation company headquartered in Irvine, California. The company specializes in advanced medical devices for cardiovascular disease management. Edwards Lifesciences has established a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1979. The company's portfolio is dominated by Cardiovascular devices, which represent 88% of all submissions. The latest clearance was received in 2026, demonstrating continued active development and regulatory engagement. Recent clea...
