FDA 510(k) Premarket Notification

CLEARED

K050627 LIFESTENT TURBO BILIARY STENT SYSTEMS

Mar 22, 2005
11 days to decision

K050627 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k050627/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 11, 2005
Decision date	Mar 22, 2005
Days to decision	11 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...