FDA 510(k) Premarket Notification

K052132 MODIFICATION TO: LIFESTENT VALEO BILIARY STENT SYSTEM

CLEARED

Aug 24, 2005
19 days to decision

K052132 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k052132/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 5, 2005
Decision date	Aug 24, 2005
Days to decision	19 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...