FDA 510(k) Premarket Notification

K013990 LIFESTITCH SUTURING DEVICE

CLEARED

Feb 27, 2002
86 days to decision

K013990 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013990/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Dec 3, 2001
Decision date	Feb 27, 2002
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	LUCINDA STOCKERT
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...