

K141206 EDWARDS LIFESCIENCES THRUPOUR KNOTTING SYSTEMJan 16, 2015
252 days to decisionK141206 · Product code: **GAW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k141206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	May 9, 2014
Decision date	Jan 16, 2015
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Nina Brooke
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k141206/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026