FDA 510(k) Premarket Notification

K163693 IntraClude Intra-Aortic Occlusion Device

CLEARED

Jan 26, 2017
29 days to decision

K163693 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k163693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Clamp, Vascular (DXC)
Date received	Dec 28, 2016
Decision date	Jan 26, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Lisa G. Hessabi
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...