FDA 510(k) Premarket Notification

K031946 EMBOL-X INTRA-AORTIC FILTER: EXTRA-SMALL, SMALL, MEDIUM, LARGE, EXTRA-LARGE

CLEARED

Nov 3, 2003
132 days to decision

K031946 · Product code: **DTM** · Cardiovascular
Source: https://www.510kdatabase.net/k031946/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Jun 24, 2003
Decision date	Nov 3, 2003
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	JEAN CHANG
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...