

K260105 Fogarty Spring Clips, Handleless Clamps, and Clamp Inserts

Jun 5, 2026
143 days to decisionK260105 · Product code: **DXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k260105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Jan 13, 2026
Decision date	Jun 5, 2026
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences
Location	Irvine, CA, US
Contact	Marcelo Piovarcsik
Website	http://www.edwards.com
510(k) history	21 submissions · 20 cleared · 2011-2026

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...