

**K153069 Edwards Balloon Catheter**Jan 7, 2016  
77 days to decisionK153069 · Product code: **OMZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153069/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulmonary (pulmonic) Valvuloplasty Catheters/percutaneous Valvuloplasty Catheter (OMZ)
Date received	Oct 22, 2015
Decision date	Jan 7, 2016
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edwards Lifesciences</b>
Location	Irvine, CA, US
Contact	CHRIS KENNELLY
Website	<a href="http://www.edwards.com">http://www.edwards.com</a>
510(k) history	20 submissions · 19 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...