

**K110167 PRESEP OLIGON OXIMETRY CATHETERS (16 CM, W/HEPARIN), (20CM, W/HEPARIN)**Feb 18, 2011  
29 days to decisionK110167 · Product code: **DQE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110167/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Jan 20, 2011
Decision date	Feb 18, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	MARGUERITE THOMLINSON
Website	<a href="https://www.edwards.com">https://www.edwards.com</a>
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](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k110167/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026