

**K254232 ECLIPTIS Left Atrial Appendage Exclusion System (ECS135)**

Jun 26, 2026  
179 days to decision

K254232 · Product code: **PZX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k254232/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	Dec 29, 2025
Decision date	Jun 26, 2026
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary
Other names	ECLIPTIS Left Atrial Appendage Exclusion System (ECS140); ECLIPTIS Left Atrial Appendage Exclusion System (ECS145); ECLIPTIS Left Atrial Appendage Exclusion System (ECS150)

**APPLICANT**

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Company	<b>Edwards Lifesciences</b>
Location	Irvine, CA, US
Contact	Corinne Yestrepky
Website	<a href="http://www.edwards.com">http://www.edwards.com</a>
510(k) history	22 submissions · 21 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...