

**K232295 LAA Exclusion System**Aug 30, 2023  
29 days to decisionK232295 · Product code: **PZX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k232295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	Aug 1, 2023
Decision date	Aug 30, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syntheon, LLC</b>
Location	Miami, FL, US
Contact	Toygar Unal
510(k) history	2 submissions · 2 cleared · 2008-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232295/> 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 26, 2026