

K220305 Syntheon LAA Exclusion System, Syntheon LAA Selection Guide

Oct 28, 2022
268 days to decisionK220305 · Product code: **PZX** · Cardiovascular
Source: <https://www.510kdatabase.net/k220305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	Feb 2, 2022
Decision date	Oct 28, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Syntheon
Location	Miami, FL, US
Contact	Sean McBryer
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Caraballo Consulting, LLC
Contact	Elena Jugo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220305/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026