

# K191413 AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip, AtriClip LAA Exclusion System with preloaded V-Clip

Aug 21, 2019  
85 days to decision

K191413 · Product code: **PZX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191413/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	May 28, 2019
Decision date	Aug 21, 2019
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>AtriCure, Inc.</b>
Location	West Chester, OH, US
Contact	Jim Taufen
Website	<a href="http://www.atricure.com/">http://www.atricure.com/</a>
510(k) history	59 submissions · 59 cleared · 2001-2025

AtriCure, Inc. specializes in surgical devices for atrial fibrillation treatment and pain management. The company develops ablation systems, left atrial appendage exclusion devices, and minimally invasive surgical instruments. AtriCure operates with a manufacturing facility in West Chester, Ohio, and serves healthcare professionals globally. AtriCure has received FDA 510(k) clearances from total submissions since 2001. The company focuses primarily on cardiovascular devices, including surgical ablation systems, LAA management solutions, and epicardial access tools. The la...