

**K163261 AtriClip PRO, PRO2, and PRO V LAA Exclusion
System devices with preloaded Gillinov-Cosgrove Clip**May 19, 2017
179 days to decisionK163261 · Product code: FZP · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Nov 21, 2016
Decision date	May 19, 2017
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	Jonathan McElwee
Website	http://www.atricure.com/
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...

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