

K153500 AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove PRO V ClipJan 27, 2016
51 days to decisionK153500 · Product code: FZP · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k153500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Dec 7, 2015
Decision date	Jan 27, 2016
Days to decision	51 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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Device record: <https://www.510kdatabase.net/k153500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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