

**K093679 ATRICLIP LAA EXCLUSION SYSTEM WITH
PRELOADED GILLINOV-COSGROVE CLIP, GILLINOV-
COSGROVE SECTION GUIDE MODEL VARIOUS LAA0**Jun 10, 2010
195 days to decisionK093679 · Product code: **FZP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k093679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Nov 27, 2009
Decision date	Jun 10, 2010
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	JAMES LUCKY
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...