

K233407 AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (LAA0)

Nov 2, 2023
28 days to decisionK233407 · Product code: PZX · Cardiovascular
Source: <https://www.510kdatabase.net/k233407/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	Oct 5, 2023
Decision date	Nov 2, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH2); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO2); AtriClip PRO-V LAA Exclusion System (PROV); AtriClip Flex-V LAA Exclusion System with preloaded V Clip (ACHV)

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	Stephanie Hadnot
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...