FDA 510(k) Premarket Notification

# K173031 AtriClip LAA Exclusion System with Preloaded PRO·V Clip

**CLEARED**

Oct 25, 2017
27 days to decision

K173031 · Product code: **FZP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k173031/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Clip, Implantable (FZP) |
| Date received | Sep 28, 2017 |
| Decision date | Oct 25, 2017 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **AtriCure, Inc.** |
| Location | West Chester, OH, US |
| Contact | Melissa Smallwood |
| 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...