

**K180010 AtriClip FLEX-V**Jan 31, 2018  
29 days to decisionK180010 · Product code: **FZP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k180010/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Clip, Implantable (FZP)
Date received	Jan 2, 2018
Decision date	Jan 31, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AtriCure, Inc.</b>
Location	West Chester, OH, US
Contact	Brittany Lowe
Website	<a href="http://www.atricure.com/">http://www.atricure.com/</a>
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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