

**K063630 ATRICURE ABLATION SYSTEM**Jan 26, 2007  
51 days to decisionK063630 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k063630/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 6, 2006
Decision date	Jan 26, 2007
Days to decision	51 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AtriCure, Inc.</b>
Location	West Chester, OH, US
Contact	ELSA C ABRUZZO
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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