

**K050459 ATRICURE ISOLATOR TRANSPOLAR PEN**Jun 13, 2005  
110 days to decisionK050459 · Product code: **OCL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050459/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Feb 23, 2005
Decision date	Jun 13, 2005
Days to decision	110 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 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...