

**K122611 COOLRAIL LINEAR PEN MODEL MCRI**Sep 26, 2012  
30 days to decisionK122611 · Product code: **OCL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Aug 27, 2012
Decision date	Sep 26, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AtriCure, Inc.</b>
Location	West Chester, OH, US
Contact	JIM LUCKY, RAC
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...