

K073605 ATRICURE COOLRAIL LINEAR PENMar 11, 2008
81 days to decisionK073605 · Product code: **OCL** · Cardiovascular
Source: <https://www.510kdatabase.net/k073605/>**SUBMISSION DETAILS**

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	Dec 21, 2007
Decision date	Mar 11, 2008
Days to decision	81 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	ALISON GRIMALDI
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...