

K192125 Isolator Transpolar Pen, Isolator Long Pen TT, Isolator Linear Pen

Nov 4, 2019
90 days to decisionK192125 · Product code: **OCL** · Cardiovascular
Source: <https://www.510kdatabase.net/k192125/>

SUBMISSION DETAILS

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 6, 2019
Decision date	Nov 4, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	Johnathon McElwee
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...

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