FDA 510(k) Premarket Notification

CLEARED

K221358 Isolator® Linear Pen (MLP1)

Dec 30, 2022
233 days to decision

K221358 · Product code: **OCL** · Cardiovascular
Source: https://www.510kdatabase.net/k221358/

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	May 11, 2022
Decision date	Dec 30, 2022
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Isolator® Transpolar™ Pen (MAX1, MAX5), Coolrail® Linear Pen (MCR1); Isolator® Synergy Surgical Ablation System (EMR2, EML2); Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide System; Isolator® Synergy Access Clamp (EMT1)

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	Jonathan 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...