

K121507 ATRICURE CRYO MODULE SYSTEM (ACM, CRYO1, AND CRYOICE)Jun 6, 2012
16 days to decisionK121507 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k121507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 21, 2012
Decision date	Jun 6, 2012
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	JAMES LUCKY
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...