

K111042 ATRICURE CRYO MODULEMay 26, 2011
41 days to decisionK111042 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k111042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Apr 15, 2011
Decision date	May 26, 2011
Days to decision	41 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	AtriCure, Inc.
Location	West Chester, OH, US
Contact	REBECCA WALTERS
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...