

**K140058 ATRICURE CRYO MODULE SYSTEM**Jan 24, 2014  
14 days to decisionK140058 · Product code: **GEH** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k140058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jan 10, 2014
Decision date	Jan 24, 2014
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AtriCure, Inc.</b>
Location	West Chester, OH, US
Contact	KARL DAHLQUIST
Website	<a href="http://www.atricure.com/">http://www.atricure.com/</a>
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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