

K152337 cryoFORM cryoICE cryoablation probeMar 22, 2016
216 days to decisionK152337 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k152337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Aug 19, 2015
Decision date	Mar 22, 2016
Days to decision	216 days
Third-party review	Yes
Summary / Statement	Summary

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...
