

K182565 AtriCure cryoICE cryoSPHERE cryoablation probeNov 9, 2018
52 days to decisionK182565 · Product code: **GXH** · Neurology
Source: <https://www.510kdatabase.net/k182565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Surgical, Cryogenic (GXH)
Date received	Sep 18, 2018
Decision date	Nov 9, 2018
Days to decision	52 days
Third-party review	No
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...
