FDA 510(k) Premarket Notification

CLEARED

K180137 AtriCure cryoICE cryo-ablation probe (CRYO3), AtriCure cryoICE cryoFORM cryo-ablation probe (CRYOF)

Feb 15, 2018
29 days to decision

K180137 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jan 17, 2018
Decision date	Feb 15, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	Melissa Smallwood
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...