FDA 510(k) Premarket Notification

K082074 ATRICURE CRYO1 CRYO-ABLATION PROBE

CLEARED

Mar 2, 2009
222 days to decision

K082074 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k082074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jul 23, 2008
Decision date	Mar 2, 2009
Days to decision	222 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	JAMES LUCKY
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...