FDA 510(k) Premarket Notification

CLEARED

K020919 ATRICURE BIPOLAR SYSTEM, MODELS ASU1, ASU2, ASU3, LHP1, LHP2, RHP1

Apr 19, 2002
29 days to decision

K020919 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k020919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 21, 2002
Decision date	Apr 19, 2002
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	MARK L FRIEDMAN
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...