FDA 510(k) Premarket Notification

K233959 EPi-Ease Epicardial Access Device (EAS)

CLEARED

Feb 13, 2024
60 days to decision

K233959 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k233959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 15, 2023
Decision date	Feb 13, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	Jenifer Ulrikson
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...