FDA 510(k) Premarket Notification

K090834 EPICARDIA 5000

CLEARED

May 15, 2009
49 days to decision

K090834 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k090834/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 27, 2009
Decision date	May 15, 2009
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicomp, Inc.**
Location	Mchenry, IL, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	23 submissions · 23 cleared · 1983-2018