FDA 510(k) Premarket Notification

K944350 SC 6000/ SC 6000P/ R50

CLEARED

Apr 10, 1995
216 days to decision

K944350 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k944350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Sep 6, 1994
Decision date	Apr 10, 1995
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	THOMAS CONNELLY
510(k) history	778 submissions · 778 cleared · 1980-2026