FDA 510(k) Premarket Notification

K921318 ADAPTING SLEEVE KIT MODEL 4023

CLEARED

Aug 3, 1992
137 days to decision

K921318 · Product code: **DTD** · Cardiovascular
Source: https://www.510kdatabase.net/k921318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Mar 19, 1992
Decision date	Aug 3, 1992
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens-Pacesetter, Inc.**
Location	Sylmar, CA, US
Contact	GLENN THOMPSON
510(k) history	7 submissions · 2 cleared · 1992-1994