FDA 510(k) Premarket Notification

K934727 REPLACEMENT PARTS FOR CPI 6888 LEAD TUNNELER

CLEARED

Jan 10, 1994
101 days to decision

K934727 · Product code: **DWS** · Cardiovascular
Source: https://www.510kdatabase.net/k934727/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instruments, Surgical, Cardiovascular (DWS)
Date received	Oct 1, 1993
Decision date	Jan 10, 1994
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
Contact	MICHELE C PURCELL
510(k) history	76 submissions · 76 cleared · 1977-2010

Cardiac Pacemakers, Inc. (CPI), doing business as Guidant Cardiac Rhythm Management, manufactured implantable cardiac rhythm management devices. Now part of Boston Scientific, the company is based in Saint Paul, Minnesota, with historical operations in McHenry, US. The company received FDA 510(k) clearances from total submissions between 1977 and 2010. Cardiovascular devices dominated the regulatory portfolio at 83% of submissions. This historical record reflects the company's core focus on cardiac rhythm management and related interventional technologies. CPI developed t...