FDA 510(k) Premarket Notification

K920601 ASTRA T2, ASTRA T4, ASTRA T6

CLEARED

Oct 28, 1992
260 days to decision

K920601 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k920601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 11, 1992
Decision date	Oct 28, 1992
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
Contact	NICK HORVATH
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...