FDA 510(k) Premarket Notification

CLEARED

K890785 ASTRA T2, T3, T4, T6 PULSE GENERATORS NEW PACKAGE

Mar 10, 1989
23 days to decision

K890785 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k890785/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 15, 1989
Decision date	Mar 10, 1989
Days to decision	23 days
Third-party review	No

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
Contact	HELEN BUCKO
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...