FDA 510(k) Premarket Notification

K912379 PDT CARRYALL TRANSMITTER, VARIOUS MODELS

CLEARED

Jun 17, 1991
19 days to decision

K912379 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k912379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 29, 1991
Decision date	Jun 17, 1991
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
Contact	CATHY YOHNK
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...