FDA 510(k) Premarket Notification

K863046 ULTRA SOFTWARE MODULE: MODEL 2016

CLEARED

Dec 5, 1986
115 days to decision

K863046 · Product code: **KRG** · Cardiovascular
Source: https://www.510kdatabase.net/k863046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Programmer, Pacemaker (KRG)
Date received	Aug 12, 1986
Decision date	Dec 5, 1986
Days to decision	115 days
Third-party review	No

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
Contact	ANN MORRISSEY
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...