FDA 510(k) Premarket Notification

K861009 BIPOLAR CARDIAC PACEMAKER, MODEL 110

CLEARED

Apr 23, 1986
36 days to decision

K861009 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k861009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 18, 1986
Decision date	Apr 23, 1986
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Cardiac Control Systems, Inc.**
Location	Mchenry, IL, US
Contact	KENNETH J DURBIN
510(k) history	26 submissions · 24 cleared · 1983-1997