FDA 510(k) Premarket Notification

K950210 CCS MAESTRO(R) II SERIES 200 MODELS 235 AND 227 CARDIAC PACEMAKER

CLEARED

May 3, 1995
104 days to decision

K950210 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k950210/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 19, 1995
Decision date	May 3, 1995
Days to decision	104 days
Third-party review	No

APPLICANT

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