FDA 510(k) Premarket Notification

K810884 #325 PROGRAMMABLE CARD. PULSE GENERATOR

CLEARED

Jun 16, 1981
76 days to decision

K810884 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k810884/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 1, 1981
Decision date	Jun 16, 1981
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Cook Pacemaker Corp.**
Location	Mchenry, IL, US
510(k) history	34 submissions · 31 cleared · 1981-1997