FDA 510(k) Premarket Notification

K812832 MODEL 325C UNIPOLAR CARDIAC PULSE GEN.

CLEARED

Nov 5, 1981
27 days to decision

K812832 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k812832/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 9, 1981
Decision date	Nov 5, 1981
Days to decision	27 days
Third-party review	No

APPLICANT

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