FDA 510(k) Premarket Notification

K792232 UNIFOCAL 3-2 MODELS UNIPOLAR & BIPOLAR

CLEARED

Nov 27, 1979
22 days to decision

K792232 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k792232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 5, 1979
Decision date	Nov 27, 1979
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**American Pacemaker Corp.**
Location	Mchenry, IL, US
510(k) history	14 submissions · 14 cleared · 1977-1982