FDA 510(k) Premarket Notification

K771262 PACEMAKER & CARDIAC LEAD, BIPOLAR

CLEARED

Jul 21, 1977
10 days to decision

K771262 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k771262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 11, 1977
Decision date	Jul 21, 1977
Days to decision	10 days
Third-party review	No

APPLICANT

Company	**Arco Medical Products Co.**
Location	Walker, MI, US
510(k) history	21 submissions · 20 cleared · 1976-1980