FDA 510(k) Premarket Notification

K800837 PROGRAMMABLE BIPOLAR CARDIAC GENERATOR

CLEARED

Jun 30, 1980
76 days to decision

K800837 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 15, 1980
Decision date	Jun 30, 1980
Days to decision	76 days
Third-party review	No

APPLICANT

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