FDA 510(k) Premarket Notification

K802588 MODEL 3003 UNIPOLAR DEMAND CARDIAC GEN.

CLEARED

Nov 19, 1980
30 days to decision

K802588 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k802588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 20, 1980
Decision date	Nov 19, 1980
Days to decision	30 days
Third-party review	No

APPLICANT

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