FDA 510(k) Premarket Notification

K800838 ARCOLITH 3022&ARCOLITH 3023 CARDIAC GEN.

CLEARED

Jun 4, 1980
50 days to decision

K800838 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 15, 1980
Decision date	Jun 4, 1980
Days to decision	50 days
Third-party review	No

APPLICANT

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