FDA 510(k) Premarket Notification

K791165 ARCOLITH 4000

CLEARED

Jul 10, 1979
15 days to decision

K791165 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k791165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 25, 1979
Decision date	Jul 10, 1979
Days to decision	15 days
Third-party review	No

APPLICANT

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