FDA 510(k) Premarket Notification

K770657 GENERATOR, PULSE, CARDIAC 2LU

CLEARED

Apr 26, 1977
19 days to decision

K770657 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k770657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 7, 1977
Decision date	Apr 26, 1977
Days to decision	19 days
Third-party review	No

APPLICANT

Company	**Edwards Pacemaker Systems**
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1977-1979