FDA 510(k) Premarket Notification

K780238 PACEMAKER, PROLITH 23U. PULSE GENERATOR

CLEARED

Mar 15, 1978
30 days to decision

K780238 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k780238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 13, 1978
Decision date	Mar 15, 1978
Days to decision	30 days
Third-party review	No

APPLICANT

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