FDA 510(k) Premarket Notification

K842193 MULTILITH PULSE GENERATORS, 1141 & 2141

CLEARED

Jan 10, 1985
220 days to decision

K842193 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k842193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 4, 1984
Decision date	Jan 10, 1985
Days to decision	220 days
Third-party review	No

APPLICANT

Company	**Ela Medical, Inc.**
Location	Mchenry, IL, US
Contact	TOM S ANDERSON
510(k) history	43 submissions · 36 cleared · 1979-2004