FDA 510(k) Premarket Notification

K882391 OPUS 3 PULSE GENERATORS MODELS 4003,4004,4023,4024

CLEARED

Nov 14, 1988
157 days to decision

K882391 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k882391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 10, 1988
Decision date	Nov 14, 1988
Days to decision	157 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