FDA 510(k) Premarket Notification

K882476 OPUS PULSE GENERATORS MODELS 3001, 3003 AND 3004

CLEARED

Sep 12, 1988
89 days to decision

K882476 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k882476/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 15, 1988
Decision date	Sep 12, 1988
Days to decision	89 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