FDA 510(k) Premarket Notification

K970072 OPUS S MODEL 4121 AND 4124 PACEMAKERS

CLEARED

Aug 29, 1997
233 days to decision

K970072 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k970072/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 8, 1997
Decision date	Aug 29, 1997
Days to decision	233 days
Third-party review	No

APPLICANT

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