

K894267 OPUS MODELS 4033 AND 4034Sep 20, 1989
90 days to decisionK894267 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k894267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 22, 1989
Decision date	Sep 20, 1989
Days to decision	90 days
Third-party review	No

APPLICANT

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

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