

K894065 OPUS MODEL 4001Sep 26, 1989
110 days to decisionK894065 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k894065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 8, 1989
Decision date	Sep 26, 1989
Days to decision	110 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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