

K883037 UNILITH 3 MODELS 7580/7583/7680/7683Jan 25, 1989
190 days to decisionK883037 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k883037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 19, 1988
Decision date	Jan 25, 1989
Days to decision	190 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

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