

K810142 ELA MEDICAL UNILITH PULSE GENERATORMay 29, 1981
128 days to decisionK810142 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k810142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 21, 1981
Decision date	May 29, 1981
Days to decision	128 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k810142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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