

**K813246 MEDICAL MULTILITH PULSE GENERA-1140**Feb 12, 1982  
86 days to decisionK813246 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k813246/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 18, 1981
Decision date	Feb 12, 1982
Days to decision	86 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k813246/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 3, 2026