

**K970072 OPUS S MODEL 4121 AND 4124 PACEMAKERS**Aug 29, 1997  
233 days to decisionK970072 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k970072/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 8, 1997
Decision date	Aug 29, 1997
Days to decision	233 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970072/>, 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