

**K841228 PULSE GENERATOR 718B & 718L**Jun 26, 1984  
96 days to decisionK841228 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k841228/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 22, 1984
Decision date	Jun 26, 1984
Days to decision	96 days
Third-party review	No

**APPLICANT**

---

Company	<b>Siemens Elema AB</b>
Location	Mchenry, IL, US
510(k) history	63 submissions · 60 cleared · 1978-2003

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k841228/> 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 May 22, 2026