

**K781178 PULSE GENERATOR MODEL 208**Sep 7, 1978  
59 days to decisionK781178 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k781178/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 10, 1978
Decision date	Sep 7, 1978
Days to decision	59 days
Third-party review	No

**APPLICANT**

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Company	<b>Elema-Schonander, Inc.</b>
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1977-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k781178/> 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 20, 2026