

**K830344 SIEMENS-ELMA PULSE GENERATOR #718**May 27, 1983  
114 days to decisionK830344 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k830344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 2, 1983
Decision date	May 27, 1983
Days to decision	114 days
Third-party review	No

**APPLICANT**

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Company	<b>Burditt &amp; Calkins-Siemens-Elema</b>
Location	Mchenry, IL, US
510(k) history	10 submissions · 10 cleared · 1976-1984

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

Device record: <https://www.510kdatabase.net/k830344/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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