

**K770135 LEAD MODIFICATION**Feb 7, 1977  
14 days to decisionK770135 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k770135/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 24, 1977
Decision date	Feb 7, 1977
Days to decision	14 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/k770135/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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