

K800387 PULSE GENERATORS MODELS 657 & 677May 2, 1980
70 days to decisionK800387 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k800387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 22, 1980
Decision date	May 2, 1980
Days to decision	70 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k800387/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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