

K801324 SIEMENS-ELEMA PULSE GENERATOR 668Dec 1, 1980
181 days to decisionK801324 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k801324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 3, 1980
Decision date	Dec 1, 1980
Days to decision	181 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/k801324/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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