

K801508 SIEMENS-ELEMA PULSE GENERATOR 625Sep 16, 1980
78 days to decisionK801508 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k801508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 30, 1980
Decision date	Sep 16, 1980
Days to decision	78 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k801508/> Data sourced from FDA 510(k) public records (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. - Generated May 22, 2026