

K770657 GENERATOR, PULSE, CARDIAC 2LUApr 26, 1977
19 days to decisionK770657 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k770657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 7, 1977
Decision date	Apr 26, 1977
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Edwards Pacemaker Systems
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1977-1979

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Device record: <https://www.510kdatabase.net/k770657/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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