

K780421 GENERATOR, PULSE, CARDIAC, IMPLANTABLEJul 7, 1978
114 days to decisionK780421 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k780421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 15, 1978
Decision date	Jul 7, 1978
Days to decision	114 days
Third-party review	No

APPLICANT

Company	Telectronics, Inc.
Location	Mchenry, IL, US
510(k) history	107 submissions · 107 cleared · 1977-1990

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Device record: <https://www.510kdatabase.net/k780421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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