

K790452 28 UNIPOLAR AND BIPOLAR PULSE GENERATORSMay 8, 1979
64 days to decisionK790452 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k790452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 5, 1979
Decision date	May 8, 1979
Days to decision	64 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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