

K791955 UNIFOCAL 1 UNIPOLAR DEMAND R WAVENov 27, 1979
57 days to decisionK791955 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k791955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 1, 1979
Decision date	Nov 27, 1979
Days to decision	57 days
Third-party review	No

APPLICANT

Company	American Pacemaker Corp.
Location	Mchenry, IL, US
510(k) history	14 submissions · 14 cleared · 1977-1982

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Device record: <https://www.510kdatabase.net/k791955/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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