

K800379 BIFOCAL 2 8200 SERIES (A,B C,D)Sep 26, 1980
217 days to decisionK800379 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k800379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 22, 1980
Decision date	Sep 26, 1980
Days to decision	217 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/k800379/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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