

K800194 OVALITH P-BP BIPOLAR CARDIAC PACEMAKERFeb 11, 1980
13 days to decisionK800194 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k800194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 29, 1980
Decision date	Feb 11, 1980
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Coratomic, Inc.
Location	Mchenry, IL, US
510(k) history	15 submissions · 14 cleared · 1976-1986

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