

K781377 OVALITH 10BPDec 4, 1978
117 days to decisionK781377 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k781377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 9, 1978
Decision date	Dec 4, 1978
Days to decision	117 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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Device record: <https://www.510kdatabase.net/k781377/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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