

K790446 OVALITH-300Jul 30, 1979
158 days to decisionK790446 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k790446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 22, 1979
Decision date	Jul 30, 1979
Days to decision	158 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/k790446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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