

K841983 COOK PACEMAKER 216 BIPOLAR CARDIAC -Jul 11, 1984
57 days to decisionK841983 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k841983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 15, 1984
Decision date	Jul 11, 1984
Days to decision	57 days
Third-party review	No

APPLICANT

Company	Cook Pacemaker Corp.
Location	Mchenry, IL, US
510(k) history	34 submissions · 31 cleared · 1981-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k841983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 5, 2026