

K810885 #326 PROGRAMMABLE CARD. PULSE GENERATORJun 16, 1981
76 days to decisionK810885 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k810885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 1, 1981
Decision date	Jun 16, 1981
Days to decision	76 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/k810885/> 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 4, 2026