

**K810884 #325 PROGRAMMABLE CARD. PULSE GENERATOR**Jun 16, 1981  
76 days to decisionK810884 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k810884/>**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	<b>Cook Pacemaker Corp.</b>
Location	Mchenry, IL, US
510(k) history	34 submissions · 31 cleared · 1981-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k810884/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026