

K953417 MINIFLEX MODEL 340, 341, AND 342 PULSE GENERATORSSep 29, 1995
113 days to decisionK953417 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k953417/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 8, 1995
Decision date	Sep 29, 1995
Days to decision	113 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953417/>; 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