

K770656 GENERATOR, PULSE, CARDIAC 20UApr 26, 1977
19 days to decisionK770656 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k770656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 7, 1977
Decision date	Apr 26, 1977
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Edwards Pacemaker Systems
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1977-1979

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k770656/> 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 9, 2026