

K842193 MULTILITH PULSE GENERATORS, 1141 & 2141Jan 10, 1985
220 days to decisionK842193 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k842193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 4, 1984
Decision date	Jan 10, 1985
Days to decision	220 days
Third-party review	No

APPLICANT

Company	Ela Medical, Inc.
Location	Mchenry, IL, US
Contact	TOM S ANDERSON
510(k) history	43 submissions · 36 cleared · 1979-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k842193/>; 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 3, 2026