

K811350 UNIPOLAR SPECTRAX IMPL. PULSE GENERAT.Jul 1, 1981
49 days to decisionK811350 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k811350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 13, 1981
Decision date	Jul 1, 1981
Days to decision	49 days
Third-party review	No

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k811350/> 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 May 15, 2026