

K812153 MEDTRONIC SPECTRAXAug 31, 1981
33 days to decisionK812153 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k812153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 29, 1981
Decision date	Aug 31, 1981
Days to decision	33 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.net

Device record: <https://www.510kdatabase.net/k812153/> 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