

**K822297 ENERTRAX MODEL 7100E**Oct 4, 1982  
62 days to decisionK822297 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k822297/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 3, 1982
Decision date	Oct 4, 1982
Days to decision	62 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k822297/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026