

**K913288 MEDTRONIC UNIPOLAR, POLY PAC LEAD-BARR
COAT COILS**Oct 17, 1991
85 days to decisionK913288 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k913288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 24, 1991
Decision date	Oct 17, 1991
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913288/> 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 18, 2026