

K853194 ERA-20Mar 11, 1987
589 days to decisionK853194 · Product code: **DTE** · CardiovascularSource: <https://www.510kdatabase.net/k853194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jul 30, 1985
Decision date	Mar 11, 1987
Days to decision	589 days
Third-party review	No

APPLICANT

Company	Biotronik Sales, Inc.
Location	Mchenry, IL, US
Contact	CAWTHON
510(k) history	41 submissions · 41 cleared · 1980-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853194/>; 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 7, 2026