FDA 510(k) Premarket Notification

K853194 ERA-20

CLEARED

Mar 11, 1987
589 days to decision

K853194 · Product code: **DTE** · Cardiovascular
Source: 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