FDA 510(k) Premarket Notification

K944966 UNIPOLAR ATRIAL TEMPORARY PACING LEAD,MODEL 6492

CLEARED

Jul 14, 1995
276 days to decision

K944966 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k944966/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Oct 11, 1994
Decision date	Jul 14, 1995
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Blood Systems, Inc.**
Location	Anaheim, CA, US
Contact	SUSAN TESMER
510(k) history	15 submissions · 15 cleared · 1988-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k944966/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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