FDA 510(k) Premarket Notification

K810643 UNIVERSAL PACING ELECTRODE KIT

CLEARED

Apr 8, 1981
29 days to decision

K810643 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k810643/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Mar 10, 1981
Decision date	Apr 8, 1981
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**Stanco Medical, Inc.**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1979-1981

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k810643/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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