

K160260 Tempo Temporary Pacing LeadOct 25, 2016
267 days to decisionK160260 · Product code: **LDF** · Cardiovascular
Source: <https://www.510kdatabase.net/k160260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Feb 1, 2016
Decision date	Oct 25, 2016
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotrace Medical, Inc.
Location	San Carlos, CA, US
Contact	Laura N. Dietch
510(k) history	1 submissions · 1 cleared · 2016-2016

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