

K242863 Bioptimal Bipolar Pacing CatheterJun 15, 2025
268 days to decisionK242863 · Product code: **LDF** · CardiovascularSource: <https://www.510kdatabase.net/k242863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Sep 20, 2024
Decision date	Jun 15, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioptimal International Pte. , Ltd.
Location	Singapore, SG
Contact	Ra Bpi
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242863/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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