

K161249 Streamline 6495 Bipolar Temporary Myocardial Pacing Lead

Aug 19, 2016
108 days to decisionK161249 · Product code: **LDF** · Cardiovascular
Source: <https://www.510kdatabase.net/k161249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	May 3, 2016
Decision date	Aug 19, 2016
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic
Location	Minneapolis, MN, US
Contact	Debra Taitague
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...

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