

K242705 Streamline Unipolar Pediatric Temporary Pacing Lead (6491) Streamline Unipolar Temporary Atrial Pacing Lead (6492) Streamline Unipolar Temporary Myocardial Pacing Wire (6494) Streamline Bipolar Temporary Myocardial Pacing Lead (6495) Streamline Unipolar Temporary Myocardial Pacing Lead (6500)

Jan 17, 2025
130 days to decision

K242705 · Product code: LDF · Cardiovascular
Source: <https://www.510kdatabase.net/k242705/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Sep 9, 2024
Decision date	Jan 17, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Debra Taitague
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...